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GRIFFITH COLLEGE

TO INVESTIGATE THE CHALLENGES ASSOCIATED WITH ADHESIVE SKIN REACTIONS IN WEARABLE ECG SENSORS

By

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A Dissertation submitted in partial fulfilment of the requirements for Masters in Medical device technology and Business

Griffith College Dublin

August 2025

Candidate Declaration

I, **Sona Thomas**, hereby declare that this dissertation, entitled "To Investigate the Challenges associated with Adhesive Skin Reactions in wearable ECG Sensors", submitted for the degree of MSc. Medical device Technology and Business, is my own original work and has not been submitted, in whole or in part, for the award of any degree or qualification at any other institution.

Throughout this research, I have diligently adhered to academic integrity standards, ensuring that any references to the work of others are duly acknowledged. All sources of information have been duly acknowledged in accordance with the Griffith College Harvard Referencing style. I have conducted through research and analysis, drawing upon various scholarly sources and methodologies. Any contributions from external sources have been appropriately cited, recognizing the intellectual property of others. I affirm that this document represents my original insights, interpretations, and conclusions derived from my personal academic endeavours.

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Signature: 

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List of abbreviations

CNTs	Carbon Nanotubes
ECGs	Electrocardiograms
MDR	Medical Device Regulation
GDPR	General Data Protection Regulation
CVDs	Cardiovascular Diseases
PSAs	Pressure-Sensitive Adhesives
AD	Atopic Dermatitis
FDA	The Food And Drug Administration
PTBP-F-R	p-Tert-butylphenol-formaldehyde Resin

Abstract

Adhesive skin responses are a major barrier to sustained and safe application of wearable ECG monitors. The study aimed to evaluate the extent of dermatological problems due to adhesive electrodes, determine their influence on the subjects comfort during long-term measurement, and develop approaches for the suppression of side-effects. In this way, the study used primary qualitative methods and thematic data analysis with 8 participants, including medical technicians and biomedical engineers, with 7 open-ended questions. The efficacy of the product was validated, as the long-term use of standard adhesive electrodes was often associated with skin redness, itching, and even more severe dermatological symptoms. These concerns greatly affected participant adherence to sensor wear and sometimes affected the accuracy of ECG reading by premature removal or dislodging of the sensor. The results also confirmed that subjects with sensitive skin were preponderantly affected, indicating that electrode materials and adhesives need to be adapted for individual users. Comparative testing also showed that hydrogel and hypoallergenic adhesives resulted in lower levels of irritation, and challenges remain in balancing strong adhesion with no discomfort during prolonged wear.This research found that minimising adhesive-related skin reactions is crucially important for enhancing the clinical utility and acceptance of the wearable ECG patch. Recommendations have involved the production of biocompatible, gas-permeable adhesive materials, the inclusion of no adhesive attachment means to attach sensors to the body, and an increased focus on personalisation in sensor design. Regulatory considerations also emerged as ignoring adhesive safety has led to non-compliance with standards, including FDA, ISO 10993, IEC 60601, HIPAA and GDPR frameworks. Overall, the study has highlighted the need to balance medical function and user comfort in the design of systems to improve compliance, data quality, and patient safety in long-term ECG monitoring.

CHAPTER 1: INTRODUCTION

1.1 Introduction

Among the global medical and other industries, wearable technologies are significant in their growth. Wearable ECG sensors, due to being convenient and smart, are widely used for cardiac monitoring both in clinics and in homes (Ramasamy and Balan, 2018). However, it is seen that these devices, after wearing them for a prolonged time, cause skin irritations. Due to its popularity among elderly and chronic cardiac patients, the dermatological side effects are a crucial concern. Hence, the research aims to investigate such skin reactions and their side effects in terms of user discomfort, clinical limitations and potential improvements to enhance user experience and the viability of these devices.

1.2 Purpose of the study

The global usage of ECG monitoring systems regarding cardiovascular health has been significant in recent years, as the benefits of these wearables are prominent and remarkable. The wearable ECG devices have improved the aspect of cardiac care by enabling continuous heart rate monitoring. According to the study ofHughes *et al.* (2023), continuous monitoring by ECG increased the rate of Atrial Fibrillation by 17.9% within 30 days from the hospital discharge. However, their prolonged usage can result in adverse skin responses such as contact dermatitis, rash and blistering, especially among the elderly population. According to the study of(Dahiya *et al.*, 2024), the usage of Ag/AgCl electrodes in the wearable ECG sensor can risk skin irritation up to 47%, compared to the OM signals used in garments that have the risk of 7%. There are instances where the patient did not comply with the monitoring protocols and removed wearables earlier due to skin irritations. Such issues interfere with the sponsor's performance and signal integrity that may further harm the treatment. The purpose of this study is to identify the specific causes of such skin irritations and assess their impacts on patient outcomes. Moreover, the study focuses on the evaluation of the clinical utility and user comfort for using the devices. Overall, the research aims to recommend design and material involvement regarding these issues to help manufacturers and medical professionals innovate safe and effective ECG wearables.

1.3 Context of the study

The rise of cardiovascular deaths has been significant over the past years. According to the study of (Di Cesare *et al.*, 2024), in 2019, cardiovascular death (CVD) globally accounted for 33% of the total deaths. Additionally, 85% of the CVD-related deaths were 9.1 million due to heart disease and 6.6 million due to stroke (Di Cesare *et al.*, 2024). This scenario of increased

cardiovascular death rates and ECG monitor effectiveness in such cases has affected the popularity of wearable ECG devices, especially among elderly people and chronically ill patients. The global wearable ECG market is currently one of the fastest-growing segments with a significant pace. In 2021, the market size crossed USD 12.28 billion and is expected to reach USD 35.45 billion by 2027(Arizton, 2023). ***Figure 1*** shows the market growth of mobile ECG wearables comparing 2024 to2030, which shows a market growth forecast at a CAGR of 10.7% (Markets, 2025).

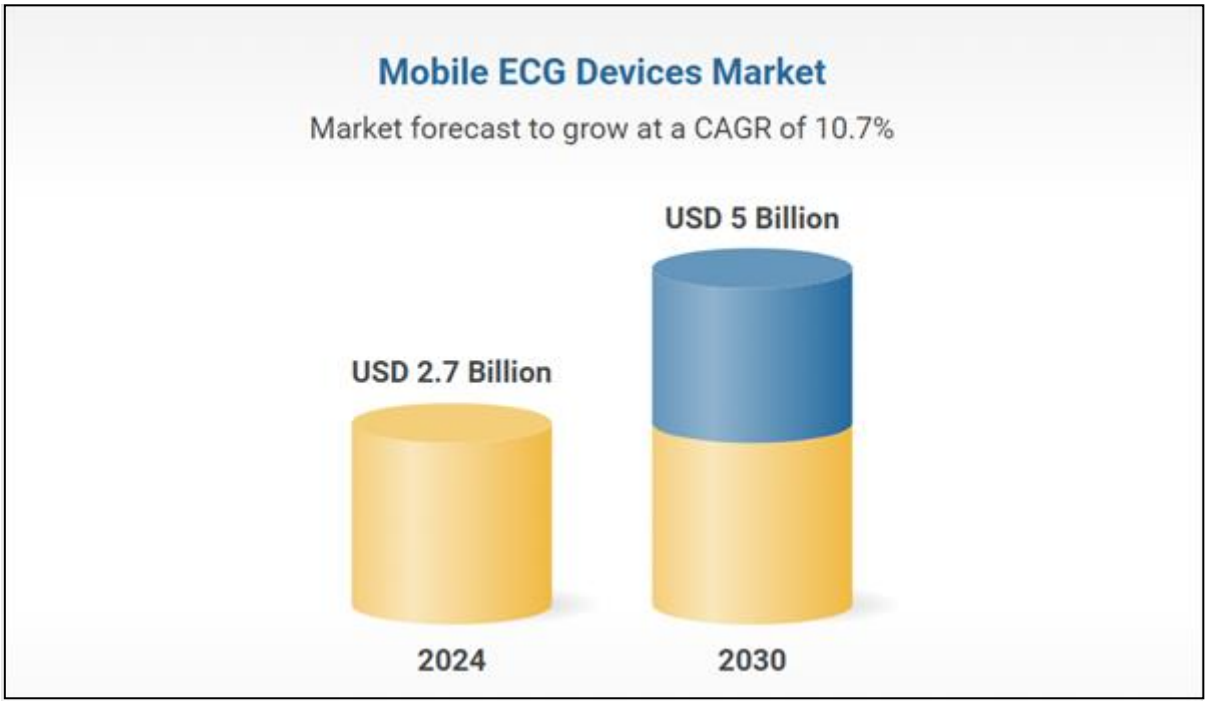

Figure 1.1: ECG mobile device market growth

(Source: Markets, 2025)

The sensors, once attached to the body, provide important cardiac data to clinicians and which helps in improving diagnosis and intervention rate. The study of Kamga *et al.* (2022) says that among female patients aged above 65, the number one complaint is chest pain and cardiac-related issues, where ECGs were ordered approximately 33,903 times. In the clinical atmosphere, it was seen that the patients receiving ECG within 10 minutes of arrival were able to get more effective patient care (Kamga*et al.*2022). However, there is very limited research on the issue regarding skin concerns, irritation and other dermatological risks due to the ECG usage. The sensors mostly use medical-grade acrylic or hydrogel adhesives to fix the devices to the body(Malesu, 2023). These devices traditionally rely upon silver or silver chloride wet electrodes, which are prone to cause skin irritation and dermatological risks(Malesu, 2023). Such materials ensure the acquisition of accurate ECG signals, while they may also cause allergic contact dermatitis or other irritants due to long-term use.

Moreover, the usage of carbon nanotubes (CNTs) and graphene in wearables also poses significant concerns regarding their toxicity (Elango *et al.*, 2023). Based on this context of skin concerns and wide usage of wearable ECGs, the research seeks to examine the current medical practices to improve their material and structure in order to make them more skin-friendly for the patients.

1.4 Significance and Justification of the Study

The increased usage of ECG wearables enabled huge benefits for patient care outcomes by enabling constant monitoring to detect any discrepancies at the earliest. New developments regarding ECG using dry electrodes are claimed to be more proficient and preventive in case of heart attacks on time(Ramsey, 2023). The study of Neri *et al.* (2023), embedding electrocardiogram monitoring and artificial intelligence, enabled greater diagnostic capabilities. Another study ofZang *et al.* (2025), evaluated the way to integrate ECG and PCG devices to improve non-invasive and intelligent monitoring of cardiovascular diseases. There have been extensive studies on various aspects of wearable ECGs, including their functional benefits and biological interface. However, the skin-related concerns regarding the usage of wearables such as ECGs are largely unexplored via research. Users with sensitive skin and pre-existing skin conditions, such as eczema wearables can cause acute infections and irritations. Such conditions further interrupt the benefits of the wearable. It is also seen that constant wearing of wearable devices that use silicone or some other cheap materials traps water on the skin, and the dampness results in irritation. Due to such irritations, patients are seen to remove the devices frequently, which disrupts the flow of monitoring, which can further lead to misdiagnosis or delayed diagnosis (Guarducci *et al.*, 2025). Several companies, such as Nahtlos, are taking initiatives to make improved electrodes to combat these challenges and enable skin-friendly adhesives.

Furthermore, in clinical settings overlooking dermatological considerations can result in negligence in user safety, which can be considered as noncompliance with the Medical Device Regulation (MDR) act (FDA, 2024). Such an implication can become a regulatory concern for the medical facility. Based on the above contexts, the study is justified as it addresses the root causes of adhesive skin reactions and offers recommendations for improvements. In case of the device innovation, reducing healthcare burdens and enhancing satisfaction of the patients, the study will significantly contribute to both the clinical effectiveness and commercial success.

1.5 Research Aim and Objectives

1.5.1 Aim

The research aims to investigate the dermatological challenges caused due to the prolonged use of wearable ECG sensors.

1.5.2 Objectives

- To identify dermatological issues, such as allergic and irritant skin reactions, due to the extensive use of wearable ECGs.
- To investigate the role of adhesive composition and physical characteristics in triggering adverse skin responses during prolonged contact with the skin.
- To identify how skin-related side effects affect user experience, particularly focusing on comfort, adhesive durability, and the quality and reliability of the ECG signal acquisition.
- To evaluate current commercial and medical approaches used to prevent skin irritation caused by ECG adhesives in wearable technologies.
- To recommend improvements regarding adhesive materials and wearable designs for better safety and tolerability of long-term ECG monitoring.

1.5.3 Questions

1. What are the skin issues related to allergy or irritation caused due to prolonged use of wearable ECGs?
2. How do the materials and structure of adhesive technologies influence skin responses?
3. How do the skin issues from wearable devices impact user experience, wear time and ECG signal quality?
4. What are the current commercial and medical approaches used to prevent skin irritation caused by ECG adhesives in wearable technologies?
5. How can the wearable designs and adhesive materials be improved for better skin safety and increased tolerability in prolonged ECG usage?

1.6 Access and research ethics issues

This research will be completed by following a mono-method qualitative approach as per the Research Onion model. This search has access to participants of medical technicians and biomedical engineers through professional networks and local institutional approvals. Ethical approvals will be acquired from the ethics committee before data collection is initiated. Informed consent will be obtained from all participants on a voluntary basis, and the right to

withdraw. Moreover, the research will be confidential and anonymised so as to ensure that no identities are revealed. Telephone interviews will be required through audiotaping and kept confidential for analytics purposes. GDPR (General Data Protection Regulation) offers provision for regulations of the processing of individual information(Carmi *et al.*, 2023). This regulation works for processing personal data, including sensitive health information, requiring researcher to ensure data to be processed transparently, fairly and lawfully. Considering this is a study involving human participants, theGDPR and privacy regulation by EU will be part of the study conduct.

1.7 Structure of the Dissertation

Chapters	Descriptions
Introduction	Chapter 1, Induction, explains the purpose of the study, the background of the context, and the significance, aim, objectives and questions of the research. It also outlines the growing challenges of skin irritation and allergic responses with prolonged ECG monitoring.
Literature Review	Chapter 2, Literature review, analyses the already existing studies on the context. Moreover, it analyses and identifies the gap in the existing studies. It has elaborated on regulatory norms, with FDA, MDR and ISO standards along with evaluation of comfort and compliance issues among users.
Methodology	Chapter 3, Methodology, explains the chosen research design, data collection method and analysis of the collected data. Further, consent confidentiality and reporting sensitive information has adhered all the ethical guidelines as well.
Findings and Discussion	Chapter 4, Findings and Discussion, summarises the key findings from the data analysis and discusses the results with evidence. Common irritants, reactions and material specific issues have been detailed in a thematic manner. Correlations have been developed between the adhesives and dermatological outcomes. It has developed implications for patient health, product innovation and improved healthcare practices.
Conclusion and Recommendations	The last chapter of Conclusion and Recommendations draws conclusions from the major findings and provides actionable recommendations. This chapter also highlights the limitations of the study and suggests scopes for future research. It has drawn conclusions on adhesive use being the most

	problematic in wearable ECG devices. It has recommended changes to clinical usage protocols for mitigating skin irritations.

Table 1.1: Dissertation Structure

1.8 Conclusion

In conclusion of the above context, adhesive devices such as wearable ECG sensors have been used widely for some years now. In both clinical and home-based cardiac monitoring, the wearable ECGs are significantly used due to their real-time data capturing capacity and usage convenience. However, there have been numerous cases of skin infections and rashes due to the prolonged and constant usage of such wearables. The major users being elderly and chronically ill patients, such dermatological side effects become crucial concerns for medical facilities and patient care systems. The chapter explains the aim, objective and significance of the study in terms of patient experience and clinical outcomes.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

A literature review is a study that analyses and summarises the body of literature in a given field of study by questioning, challenging, and building on existing knowledge for the purpose of informing the knowledge-building efforts of a group. In this way, this literature review provides a broad understanding based on the existing literature and focuses on the research topic: "Adhesive skin reactions associated with wearable ECG sensors". It compiles the results of multiple studies in order to support these research aims and to provide a rationale for continued investigation. The review serves as refinement work that identifies gaps in existing knowledge and informs the development of the research design and methodology, building on the preceding work. The review is based on scientific studies found in literature propagated through the scientific databases PubMed, MDPI, ScienceDirect, Wiley and others from Google Scholar. This review highlights adhesive issues, cutaneous reactions, practical considerations, corrective strategies, regulatory aspects, and new developments. The review reveals a research gap in current knowledge and encourages the setup of a conceptual framework for future study.

2.2 Overview of wearable ECG sensors

Wearable medicinal devices have been positively applied to various locations of the body, such as the head, limbs and torso. Wearable electrocardiogram (ECG) sensors were widely applied as real-time and continuous heart monitoring systems in non-traditional clinical settings to facilitate early prevention and management of cardiovascular diseases(Dahiya *et al.*, 2024b). These wearables were worn on different parts of the body, including the chest, wrist and limb, and give a cost-effective and user-friendly way to monitor heart health. Moreover, wearable ECG devices possess the potential to provide chronic disease monitoring and rehabilitation (Jafleh *et al.*, 2024). For example, various commercially available wearable ECG devices, such as smartwatches, smart scales, handheld recorders, and patches, exemplify the amalgamation of ECG technology into different consumer health products being developed to provide real-time cardiac monitoring ***(Refer to Figure 2).*** However, the use and acceptance of wearable ECG devices have remained limited due to challenges such as poor comfort, unreliable data, and limited cost-effectiveness, particularly affecting acceptance among elderly users (Ferguson *et al.*, 2021). Conversely, good patient education and ergonomic design of wearable ECGs have improved data quality and reduced the rate of

undetected atrial fibrillation (Kamga *et al.*, 2022). There is a broad agreement to make a good balance between clinical-grade accuracy and portability.

Figure 2.1: Selection of wearable ECG

(Source: Avelino *et al.*, 2025)

Traditional ECGs utilise a 12-lead system(3 standard limb leads, six precordial leads and 3 augmented limb leads) that offers comprehensive views of the electrical activities of the heart from different angles, whereas some advanced wearable ECG devices can simulate up to 56 leads by applying AI-based extrapolation. These mainly depend on inferential modelling instead of using direct multi-vector recordings (Avelino *et al.*, 2025).For instance, R-wave detection and monitoring have been the primary functionality of already existing devices, such as Apple Watch, Fitbit Sense, and they have not collected full ECG signals, including P, QRS, and T waves, that limits their diagnostic capabilities to arrhythmias (Pay, 2023). Furthermore, the American Heart Association has suggested having ECG sampling rates not less than 500 Hz in order to ensure accurate ECG detection (Avelino *et al.*, 2025). However, many wearable ECG devices have offered rates from 100 Hz to 350 Hz that affected the accuracy of measurement, in particular for paediatric or critical cases (Huhn *et al.*, 2022). This signifies that wearable ECG devices still require substantial improvement in signal quality, wearing comfort, diagnostic ability, and accessibility in order to enable widespread

decentralisation of cardiac care, through continuous innovation and their integration with AI platforms.

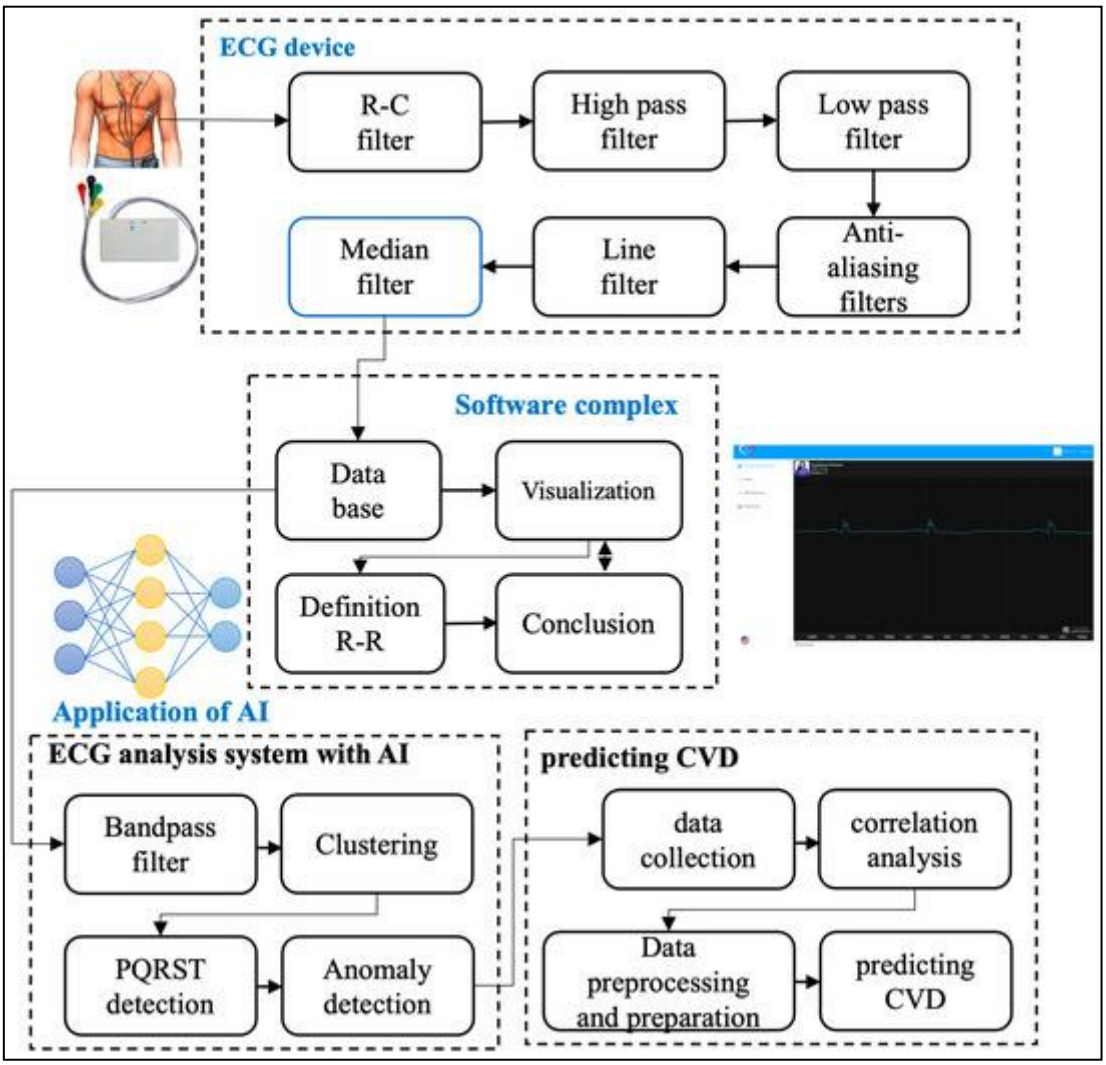

Figure 2.2: Structure of an ECG wearable system

(Source: Alimbayeva *et al.*, 2024)

Figure 3 presents an overall architecture of a wearable ECG sensor system based on hardware signal filtering, software data processing and AI-based cardiac analysis. The ECG device processes the signal via several types of filters, such as R-C, high-pass, low-pass, anti-aliasing, as well as median and line ones for noise suppression (Dobrev *et al.*, 2025). In this aspect, data is subsequently visualised and interpreted through software that allows for monitoring in real-time. Accordingly, intelligent algorithms were applied to detect anomalies, group signal patterns and predict cardiovascular diseases (CVDs) (Muzammil *et al.*, 2024). Thus, the wearable ECG devices have enabled continuous monitoring, early surveillance of heart diseases and AI-based personal diagnostic services in the non-clinical pathway have

making it possible with wearable ECG systems, enabling easy access and efficient operation for users.

2.3 Analysis of different types of adhesives used in wearable ECG devices

Wearable ECG monitors have mostly depended on skin-adhesive electrodes to ensure continuous contact with the skin for accurate cardiac signal acquisition. Adhesive type is critical to the efficacy and user comfort of such devices that, in turn, impact skin compatibility, wearability, signal quality, and user compliance (Kwon *et al.*, 2021). Similarly, wearable ECG devices utilise various adhesive materials to ensure secure electrode attachment to the skin for accurate heart monitoring. Accordingly, common adhesive materials are hydrogels, silicones, acrylics, conductive adhesives and pressure-sensitive adhesives (PSAs) that vary with intended wear time, skin type, and target application area, including dry and wet conditions (Bashir *et al.*, 2020). It has been stated that the choice of adhesive is necessary for a balance between signal reliability, skin shielding and user wellbeing for a wearable ECG device that is to be used effectively over the long term. Moreover, hydrogel adhesives are one of the most popular in commercial ECG patches due to their high-quality conductivity and biocompatibility (Yao *et al.*, 2022). Hydrogels were observed to experience a sustainability loss in water content for extended wear duration within 24 hours, causing a decrease in R-peak amplitude and an increase in noise from gel drying, especially in the case of high humidity or physical activities (Kim *et al.*, 2022). Despite this, screen-printed wet ECG electrodes with a hydrogel type composition have provided less skin irritation and better signal stability than some of the commercial equivalents ***(Refer to Figure 4)***.

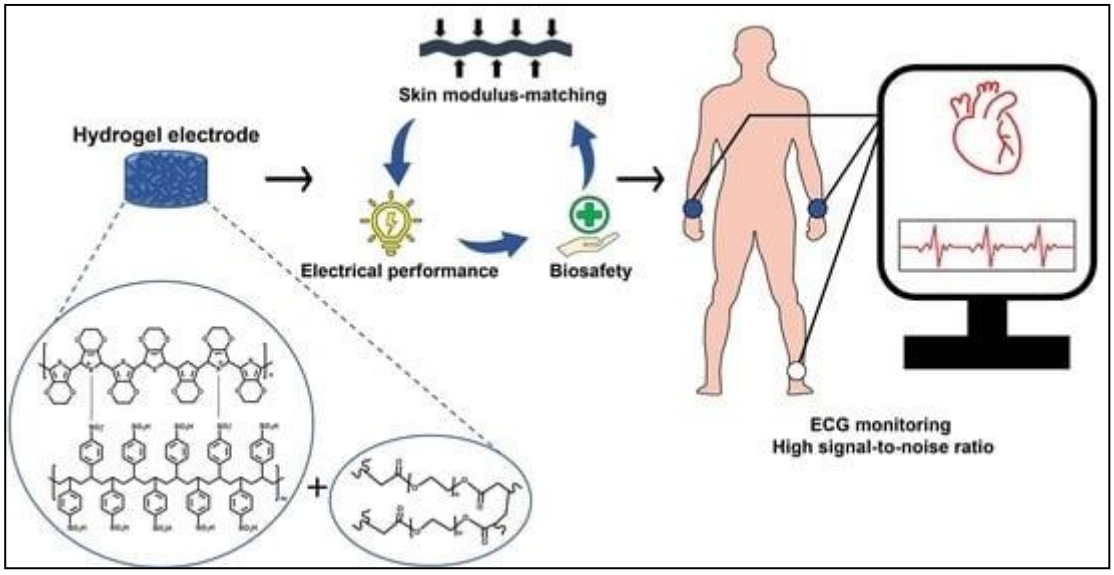

Figure 2.3: Hydrogel electrodes for wearable ECG monitoring

(Source: Lee *et al.*, 2023)

Acrylic adhesive, frequently used for longer duration ECG monitoring, including ZioPatch, provided higher adhesive strength and water resistance that make them suitable for ambulatory or water applications (Kamga *et al.*, 2022). On the other hand, hydrogel adhesive loses water content, particularly over 24 hours, which leads to drying effect and diminished adherence with long-term wear(Dahiya *et al.*, 2024b). As a result, R-peak amplitude has decreased by a large percentage and baseline noise increases significantly, especially with sweat, humidity or motion-related conditions. Based on these drawbacks, some advanced designs, such as screen-printed wet ECG electrodes with hydrogel matrices, have shown improvements in longevity and reduced skin sensitisation while contrasted to their conventional alternatives (Rauf *et al.*, 2024). Furthermore, silicone adhesive has flexibility, gentle peel-off and long-term biological compatibility (Lee *et al.*, 2017). They were ideal for those with sensitive skin or ageing skin, as it pertains to a device used by seniors. These electrodes, the silicone-based ones that even be worn for several days without causing an allergic reaction or leaving residue. In contrast, their lower tackiness has resulted in reduced adhesion during intense physical activity that risks signal disruption (Liu *et al.*, 2017). In this way, it has been signified that their reusability and ease of application have offered practical benefits in ambulatory and home-monitoring environments.

ECG wearable sensors are routinely subject to sweat, humidity, and extended skin contact that can undermine specific adhesives and compromise monitoring accuracy. Moreover, Acrylic adhesives feature a high degree of chemical resistance and resistance to moisture that makes them suitable for application in environments (Akhavan-Safar *et al.*, 2023). These are consistently exposed to moisture and exercise. These adhesives have effective wear performance and are chosen for their tendency to remain intact over long wear periods. Conversely, acrylic adhesives have been caused in their adhering that cause irritation in some individuals, especially when worn for long durations (Bloria *et al.*, 2020). Their stiffness has an impact on breathability, and discomfort is experienced when wearing them for extended periods. On the other hand, dry and PSA have made wearable ECGs available for challenging areas. Bio-inspired dry adhesives, such as geckos and octopuses, were capable of strong, repeatable, non-irritant attachment events in wet or mobile environments (Kang *et al.*, 2021). Moreover, pressure-sensitive adhesives have provided immediate stick for quick application and set-up ease to enhance patient comfort (Kim *et al.*, 2022). These types of adhesive have

improved signal stability, reduced motion artefacts and support long-term monitoring that makes ECG devices more conducive to daily and clinical use.

2.4 Assessment of dermatological reactions and risk factors in long-term use

Adhesive is necessary for wearable ECG devices to keep electrode-skin contact and obtain reliable signals. Excessive or improper application of some glues has been associated with dermatological complications (Yang *et al.*, 2024). Most frequently, hydrogel, silicon, acrylics and dry adhesives, either with pressure-sensitive or bioinspired behaviour, have been utilised as adhesives (Tiu *et al.*, 2019). Each adhesive has its own skin characteristics, moisture absorption and mechanical and immune properties.Long-term skin contact with adhesives in wearable ECG monitoring devices also has significant dermatological risks, particularly when used for monitoring over prolonged periods of time (Mao *et al.*, 2023). The most common reported side effects were irritant contact dermatitis (ICD) and allergic contact dermatitis (ACD), both related to continuous exposure to the adhesive, to entrapment of moisture by the adhesive, and to lack of recovery time before consecutive uses (Patel and Nixon, 2022). Moreover, during long-term use, the hydrogel adhesives were advantageous in terms of conductivity, but tend to cause maceration, especially in warm and humid climates (Bilić, 2018).Based on these, the moisture accumulated beneath the gel reduced the integrity of skin barriers, thereby increasing the erythema, itching and desquamation. In this way, hydration loss from the hydrogel matrix during the first 24 hours has been identified as the primary cause of adhesive breakdown against leaved skin susceptible to irritation and microbial penetration (Norahan *et al.*, 2023). These reactions were more pronounced with physically active users or sensitive skin.

Acrylic adhesives are also associated with a higher potential for delayed hypersensitivity reactions due to their strong adherence. Repeated exposure over time has sensitised the individual and led to vesicular ACD and disseminated eczema (Tramontana *et al.*, 2023). Further, micro-abrasions due to repeated application and retraction contribute to the risk of localised inflammation and infections (Tinoco *et al.*, 2025). These adverse effects have been especially severe in elderly consumers owing to increased skin fragility and impaired barrier properties. However, silicon glues have produced mechanical friction in wear areas, but are less aggressive. Silicon glues have not worked as well on sweaty skin or on oily skin types, and users will throw another occlusive tape on top and inadvertently damage the skin (Dyson *et al.*, 2023). In addition, for the use of dry adhesive technologies, inadequate adhesion in areas of moisture or movement has led to slippage, requiring frequent reapplication that is

itself a source of frictional dermatitis (Ho *et al.*, 2023). For example, pressure or suction-based attachment systems have caused mild erythema andedema that have especially developed during long-term usage (Mondal *et al.*, 2020). It has been stated that dermatological reactions have been exacerbated by risk factors, such as sweat retention, pre-existing dermatological conditions, including eczema and psoriasis, long continuous wear and poor skin hygiene. Accordingly, patients with fragile skin, such as diabetics or burn patients, who have been at greater risk of ulceration or infection beneath the adhesive (Ho *et al.*, 2023). Therefore, the use of adhesion has to create skin irritations, inflammations and allergic responses that decrease user comfort, signal quality and long-term device adoption in the cases of wearable ECG devices.

2.5 Assessment of Mechanisms of skin irritation and allergic responses

Wearable ECG devices cause skin irritation and allergic reactions due to several mechanisms. According to Mao *et al.* (2023), health information can be obtained from skin using sensors in a non-invasive manner through neural electrical signals, photoelectrical signals, thermoelectrical signals and mechanical pressure signals. Thus, skin-wearable health monitoring devices and their outlook for future development remain promising with the use of stretchable non-invasive skin-wearable electronics. In contrast, Khan *et al.* (2024), explored biosensor technology in the management of atopic dermatitis (AD) as it provides ease of access to the skin and effectively monitors dynamic changes in cutaneous features in diagnosis. Therefore, wearable skin sensors must be developed with materials that have an effective interface with skin without causing discomfort and adhere closely to skin or are penetrative in a smaller manner for not avoid allergic reactions. Further, Groot *et al.* (2024), have explored aspects of subjective allergic contact dermatitis to glucose sensors and insulin. In contrast,Dahiya *et al.* (2024), have explored that wearable ECG devices with long-term usage often cause “on-body path” and minor skin irritation issues. Therefore, wearable medical devices have a minor impact on skin irritation. According to Rauf *et al.* (2024), ECG electrodes have been gentle on the skin with easier removal than typical commercial ECG electrodes that avoid skin damage or irritation. In contrast, Taguchi *et al.* (2020), explored allergic reaction reports related to ECG electrodes due to the presence of substances like p-Tert-butylphenol-formaldehyde resin (PTBP-F-R), gum tragacanth, acrylates, para-chloro-meta-xylenol and acrylates. Thus, the presence of these substances in BIS (BI spectral Index) sensors increases dermatitis event changes. In such cases, primarily the adhesive part of the BIS sensor was found to be the primary reason for such a dermatitis patch. Further, Song *et*

al. (2024), highlighted that wearable electronics for health monitoring have silk-based constituents utilised within the assembly of wearable sensors and the use of adhesive for the detection of essential physiological indicators, like the temperature, body fluids, ECG and electromyogram, respiration, sericin and pulses. These factors play a significant role in addressing issues related to discomfort reduction, signal fidelity improvement and facilitation of medical treatment ***(Refer to figure 5).***

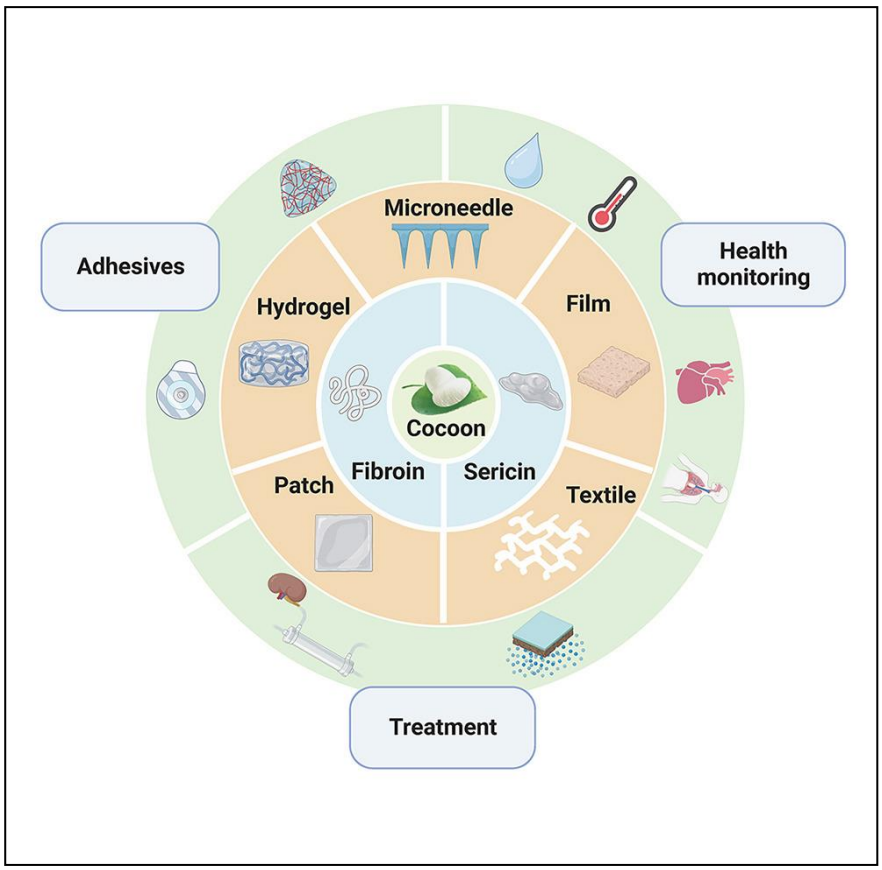

Figure 2.4: Individual-centredhealth monitoring

(Source: Song *et al.*, 2024)

Further, adhesives used to develop wearable ECG devices can cause skin irritation through chemical and mechanical means. For instance, gel used within the commercial electrodes for the reduction of contact impedance may cause skin irritation after long-term measurements (Wu *et al.*, 2020). According to Tarar *et al.* (2020), stretchable mechanical sensors need additional disposable components like adhesives that are functional until the stratum corneum regenerates.. In contrast, Vidhya *et al.* (2023), explored that the poor quality ECG wearable devices in the long term can lead to irritation in the skin as the gel present in the electrodes gets dehydrated due to the use of Ag/AgClelectrodes. Therefore, focusing on alternative electrode solutions would be very necessary to overcome the shortcomings of these wet

electrodes. Further, factors like wear, temperature, friction, and occlusion can negatively impact the wearable ECG devices and affect the abilityof devicesto maintain good skin contact (Odeh *et al.*, 2024). Additionally, sweat can affect the skin condition, moisture levels, presence and friction of the body part with wearable devices. For instance, Sweat can cause skin irritation, infection and corrosion if not properly managed with the help of wearable technology and materials (Seçkin *et al.*, 2023). Therefore, external environment-led conditions can have an impact on the variability of the wearable ECG devices and their impact on allergic responses. According to Brönneke *et al.* (2021), regulatory standardisation and supervision remain essential, and thereby medical devices need to be "FDA (The Food and Drug Administration) registered", " FDA cleared" and/or "FDA approved" depending on the risk classification for their adoption in the wider population.In contrast, Brönneke *et al.* (2021), explored European Union regulation for medical devices, where manufacturers need to declare application and adherence with regulations and standards. Therefore, strong regulatory compliance and policy framework ensurethedevelopment of quality wearable medical devices that limit events of allergic responses.

2.6 Impact of dermatological effects on user experience and ECG data quality

The dermatological reactions caused by long-term adhesion in wearable ECG systems have affected not only user comfort and compliance, but also the accuracy with which the signal is recorded. Frequently, continued use has resulted in irritation, discomfort and inflammation if the skin is discouraged from sustained use and diminishing the overall effectiveness of the device (Taji *et al.*, 2014). These issues were particularly critical in the clinical or at-home settings where continuous monitoring is crucial. However, patient compliance deteriorated due to discomfort and concern regarding adverse skin effects (Ferguson *et al.*, 2021). Despite hydrogel adhesives being preferred for their high conductivity, they have also caused maceration, erythema and skin barrier disruption owing to water accumulation and gel drying, thought to be more significant under humidity and wet conduction (Firlar *et al.*, 2022). For example, hydrogel electrodes during 48-hour records have a signal-to-noise ratio (SNR) drop of at most 35% after 24 hours, with some recordings, especially using motion or sweating (Rauf *et al.*, 2024). This has a major impact on comfort and long-term tolerability. In contrast, screen-printed hydrogel electrodes were more skin-friendly and revealed equivalent signal quality compared to commercial Ag/AgCl wet electrodes upon blinded evaluation by a cardiologist (Kim *et al.*, 2022). In addition, the user option showed score 9.1/10 for ease of removal and 0.35/10 for pain with gentle-to-skin screen-printed electrodes,

as against 5.4/10 and 4.7/10 respectively with commercial Ag/AgClelectrodes (Rauf *et al.*, 2024). This clear difference highlighted the impact of adhesive composition on user acceptability and compliance.

Dry electrodes, although non-irritating and easier to apply, usually face the problems of high skin-electrode impedance and extreme motion artefacts, especially for physical activity. However, the comparison has indicated that the solid electrodes, such as stainless steel and platinum, exhibited higher SNR and more stable performance than porous ones (Joutsen *et al.*, 2024). Dry electrodes have performed well in short-term stationary tests; however, the performance drops significantly while motion is introduced, suggesting a skin-safety against data reliability trade-off (Niso *et al.*, 2022). While it comes to perceived comfort, user feedback has brought a critically important difference. Genre-to-skin screen-printed electrodes were rated much easier to remove and less painful in comparison to commercial-type; this information has indicated the importance of dermatological comfort (Rauf *et al.*, 2024). This has significantly affected user satisfaction and acceptance to keep using the product. Accordingly, irritation and sensation of discomfort due to adhesive ECG electrodes were inconvenient for the patient, reduced patient adherence more and increased the probability of premature device extraction (Kwon *et al.*, 2021). This constantly interrupts the ECG signals, has a negative impact on the quality of the ECG signal and reliability and forms an obstacle to successful personal and clinical monitoring of the heart.

2.7 Evaluation of commercial and medical approaches to mitigate skin reactions

Skin reactions or irritation from wearable ECG devices, particularly with prolonged use,raise significant concerns for both users and healthcare professionals. According to Ma *et al.* (2024), commercial utilisation of skin-friendly electrodes, like epidermal electrode engineering with the electrospinning method, helps with the mitigation of skin reactions. These electrodes, developed from breathable materials, allow for ventilation and better sweat evaporation. For instance, electrodes made from laser-scribed graphene offer extremely thin and breathable solutions, making them effective for obstructing perspiration (Yang *et al.*, 2022). Further, Pullano *et al.* (2022), explored the use of dry electrodes that offer promising solutions for the mitigation of skin irritation, which has been a common issue with traditional wet electrodes, by eliminating the need for skin preparation like gel applications. However, the application of dry electrodes remains opaque and thereby causes skin irritation and posesasignificant concern. In contrast,Rauf *et al.* (2024), explored the utilisation of a biocompatible adhesive that creates soft adhesion and easier release from skin, thereby

making the ECG electrodes more gentle on the skin and easier to remove than typical commercial ECG devices ***(Refer to figure 6).*** Therefore, the use of biocompatible materials or gels for wearable ECG readout devices for health monitoring offers effective solutions to avoid skin irritation, along with lower costs of manufacturing, ensuring mass-scale production and adoption.

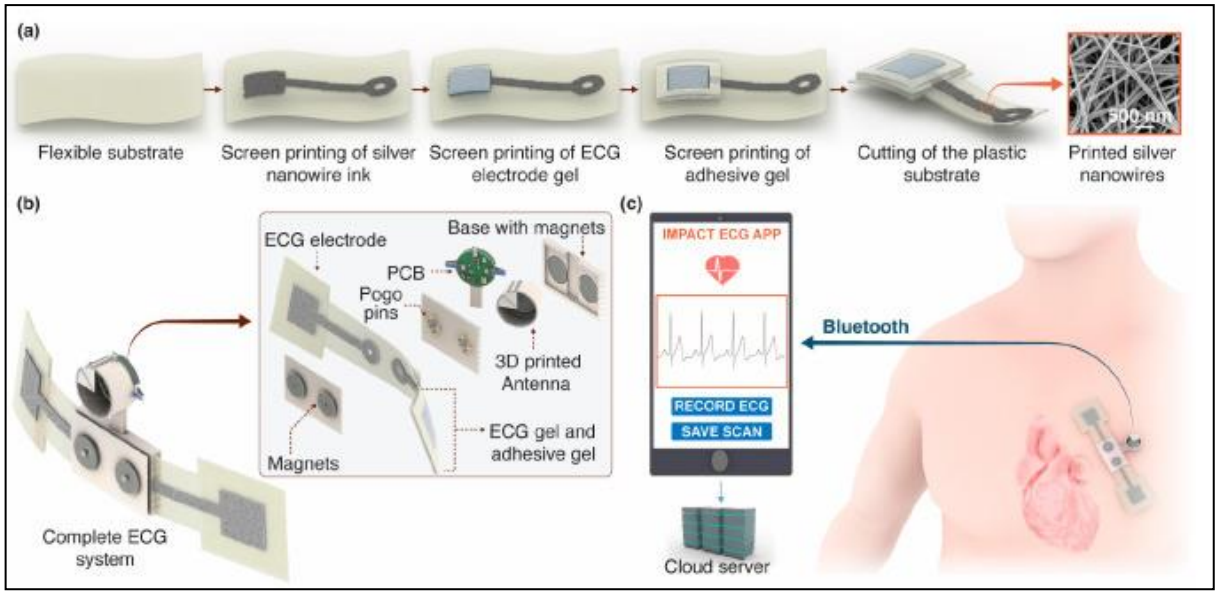

Figure 2.5: ECG electrodes with miniaturised ECG readouts

(Source: Rauf *et al.*, 2024)

The biocompatible adhesive gel creates a soft adhesive that ensures easier release from skin to avoid skin damage or irritation. Further, Chen *et al.* (2021), explored the utilisation of semi-disposable ECG systems based on the self-adhesive ECG sensor patch that has applications for reduced skin issues. In contrast,Yamamoto *et al.* (2017), explored the effect of film thickness for skin temperature measurements, the reliability of gel-less ECG sensors and the adhesive force that helps to avoid skin reactions. Therefore, commercial approaches that utilise biocompatible materials and minimise skin stripping and dermatitis issuesare required.

Clinical protocols for avoiding skin irritation from wearable ECG devices include the use of creams, adherence to rotational policies and conducting regular skin check-ups and hygiene practices. According to the National Clinical Guideline Centre (UK) (2014), skin care protocols with the use of cleansers, barrier creams/barrier films, along foam cleansers have been found to be more cost-effective than other solutions to avoid skin irritation. In contrast,Xiao *et al.* (2021), explored regular changing of electrode placement that allows for skin effective recovery and reduction of irritation likelihood. These medical approaches offer significant opportunities for the mitigation of skin irritation issues. According to Gabros and

Zito (2023), topical corticosteroids serve as the cornerstone for the management of inflammatory and pruritic dermatologic conditions. This medication is applied to reduce inflammation and has often been recommended by healthcare professionals for the mitigation of severe irritation issues, including allergic contact dermatitis, erythema and irritation contact dermatitis. In contrast,Garg *et al.* (2021), have explored the use of patch testing that indicates the gold standard for diagnostic tools for cell-mediated type IV hypersensitivity reactions with allergic contact dermatitis. Therefore, medical approaches of topical corticosteroids and patch testing offer significant opportunities to cure or prior detection of skin conditions prior to avoid chances of skin irritation from wearable ECG devices.

2.8 Review of regulatory and safety considerations

Regulatory and safety considerations ensure the successful and comfortable long-term use of wearable ECG devices. Regulatory bodies in different regions ensure quality standards are met in the safety elements of medical devices. According to Bretthauer *et al.* (2023), the European Union has introduced stringent provisions for medical devices under the Medical Device Regulations to ensure quality and safety considerations. It offers a comprehensive framework that governs the design, manufacture, and placing of medical devices within the European Union markets to ensure the safety of high-risk devices. In contrast,FDA (2023),has reported regulations brought by the FDA (The Food and Drug Administration) in the form of EUAs (Emergency Use Authorisation) for certain remote or wearable patient monitoring devices that contribute towards increasing the availability of monitoring and treatment of patients. However, Sifaoui and Eastin (2024),have explored that commercial wearable health devices do not fall under the FDA oversight. Therefore, it indicates regulatory gaps in the comprehensive monitoring of safety and quality standards for wearable health monitoring devices. According toSharma and Luthra (2023),ISO 10993 offers standards for the evaluation of biocompatibility of medical devices by introducing various tests like cytotoxicity, sensitisation and irritation. In contrast,Grob *et al.* (2015), explored IEC 60601-1 regulations for medical electrical equipment that refer to internationally recognised standards for ensuring safety and essential performance of medical electrical equipment. Therefore, international and regional regulations and authorities have developed a comprehensive framework for ensuring the quality and safety of medical device equipment.

Further, there are ethical implications for ignoring skin compatibility with wearable medical devices, as it deals with patient monitoring, encompassing continuous health tracking and remote patient monitoring. According to Anaya *et al.* (2017), patient surveys have

demonstrated ethical concerns surrounding wearable medical devices regarding privacy issues, and consideration of informed consent as an “important” factor for sharing personal information with third parties. Thus, consumers have expressed the need for shorter privacy policies that are easier to read and have a more understandable consent form that involves regulatory authority and the presence of legal consequences as well. In contrast,Pane *et al.*(2019), have explored the utilisation of post-market surveillance (PMS) recommended by the FDA and EU MDR to have transparency with manufacturers regarding the chemical composition of adhesives and gels that especially present higher skin irritation**.** Therefore, PMS serves as an effective regulatory policy framework that offers comprehensive oversight on quality manufacturing processes to avoid the chances of skin irritations.

Further, manufacturers need to comply with biocompatibility and safety standards for developing wearable ECG devices. According to Lu *et al.* (2023), the use of Bio-multifunctional smart wearable sensors for medical devices for precisely monitoring vital signs of human wellbeing by establishing a healthy, secure and reliable medical device manufacturing process. In contrast,Lu *et al.* (2023), have explored mechanical biocompatibility and immune biocompatibility, which are the basis of safety and stable work of wearable healthcare systems. Therefore, established protocols and frameworks ensure manufacturers comply with biocompatibility and safety standards.

2.9 Theoretical underpinning

2.9.1 Technology acceptance model (TAM)

TAM describes ways users come to accept and are persuaded to use a technology (Davis, 1989). TAM consists of two main factors, such as perceived usefulness (PU) and perceived ease of use (PEOU) that influence attitude towards using the technology, intention to use and in turn actual usage ***(Refer to Figure 7)***. In the context of wearable ECG devices, PU refers to the user's trust in the device to aid in health monitoring, and PEOU refers to ways convenient, discomfort-free the device is during operation.

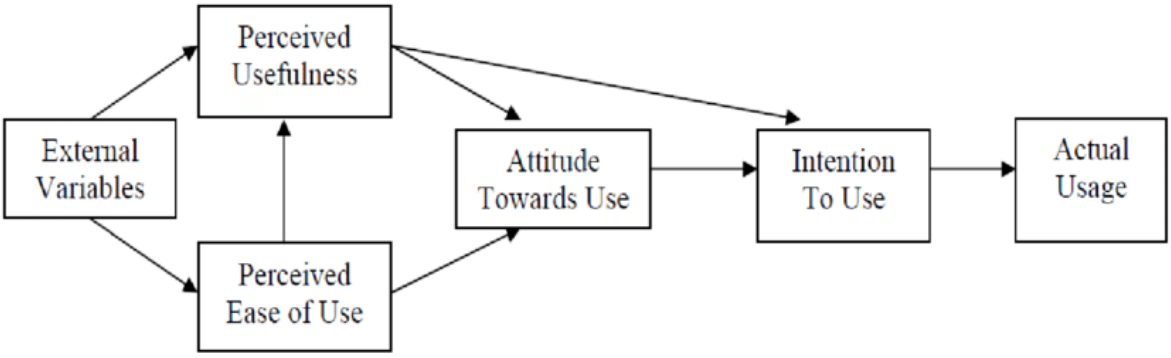

Figure 2.6: Technology acceptance model

(Source: Lai, 2017)

In practical applications, skin irritation, allergic reaction, and discomfort led to a negative influence of PU and PEOU. For example, while the adhesives were responsible for allergic contact dermatitis and maceration, the user perceived the device to be less comfortable to less beneficial and is less likely to use it (Lin *et al.*, 2018). Experiential perception has an influence on attitude towards the use of a device that forms a direct intention to use and actual use behaviour, especially in long-term monitoring. In this way, these applications of TAM have helped explain the behavioural consequences of skin problems. Skin-induced side effects affect PEOU, and a lack of adhesion performance decreases PU. These two effects have influenced tripe outcomes, including user experience, wear time and quality of the ECG signal and ultimately determine the wearable ECG technology acceptance.

2.9.2 Health Belief Model (HBM)

HBM consists of six applications, including perceived susceptibility, perceived benefits, perceived barriers, perceived self-efficacy and cue to action (Becker, 1974)***(Refer to figure 8).*** In the context of wearable ECG devices, perceived susceptibility and severity are relevant while users acknowledge the risk and discomfort of long-term skin contact with consequences, such as allergic reactions and dermatitis.

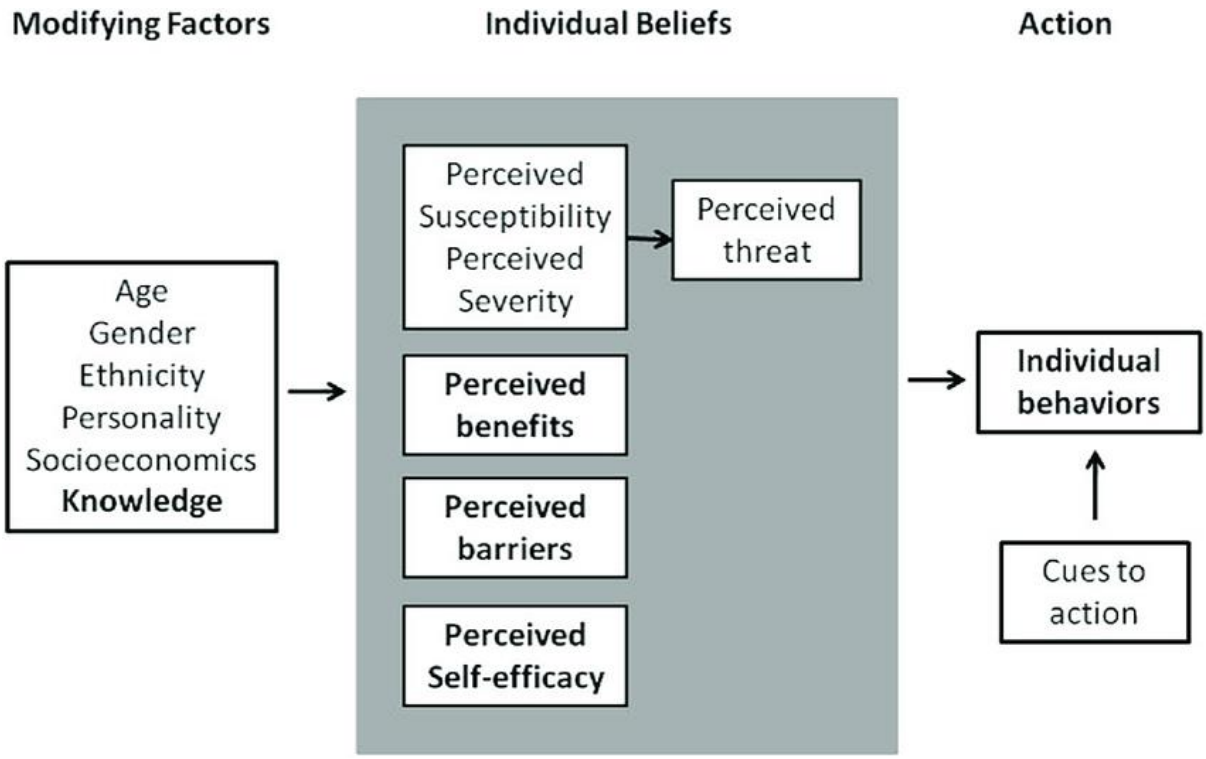

Figure 2.7: Health Belief Model

(Source: Miri *et al.*, 2018)

Perceived benefits regarding improvements associated with wearable ECG designs for safer skin interactions, including silicone-based or bioinspired adhesives to reduce irritation. Barriers, fears of pain, application concerns and cost that affected the adoption of other patterns. They have described cues to action, such as clinical recommendations and dermatological diagnosis and product labelling, as influencing behaviour to choose hypoallergenic alternatives. For example, medical-grade adhesive that has been tested for low irritation rating or screen-printed hydrogel patches that serve as cues (Shen *et al.*, 2022). In this way, self-efficacy, the convenience in the ability to use the device safely, also improved with user education and improved design, including breathable development, reusable adhesive and moisture-resistant materials. Thus, these factors are constructed and help users to adhere to long-term ECG monitoring if they feel that the devices are safe and manageable, thus improving clinical outcomes and technology adoption.

2.10 Literature gap

Most of the existing studies have focused on signal accuracy, data transmission and others, often overlooking patients' comfort and biocompatibility, especially for individuals having sensitive skin and long-term wear requirements. Most of the existing studies have primarily emphasised signal accuracy, data transmission, and related aspects, thereby neglecting patient comfort and biocompatibility, particularly for individuals with sensitive skin. Additionally,

most of the studies have focused on adhesive or raw materials for the development of ECG devices.For instance, Bashir *et al.* (2020)&Kwon *et al.* (2021), have focused on adhesive skin types and their development material for analysis of the impact on skin irritations. Therefore, a lack of observational studies that explicitly provide insights into dermatological issues linked to prolonged use of wearable ECG devices across diverse skin types remains. Further, existing studies primarily focus on manufacturers' end and use of different materials like acrylics, silicones and hydrogels for the development of adhesives and medical devices. For instance, Bashir *et al.* (2020)&Yao *et al.* (2022), have explored the use of hydrogels, silicone, and conductive adhesives and their impact on skin based on time of usage. Therefore, comparative analysis on chemical composition and physical properties that correlate with skin reaction severity remains missing. Additionally, limited research has been conducted to explore the interplay between dermatological side effects, device usability and ECG signal reliability. Therefore, the current research addresses these gaps through empirical research and establishes preventive approaches to avoid skin irritation, assess wearable rotation practice and use of dry electrodes in improving patient tolerability.

2.11 Conceptual framework

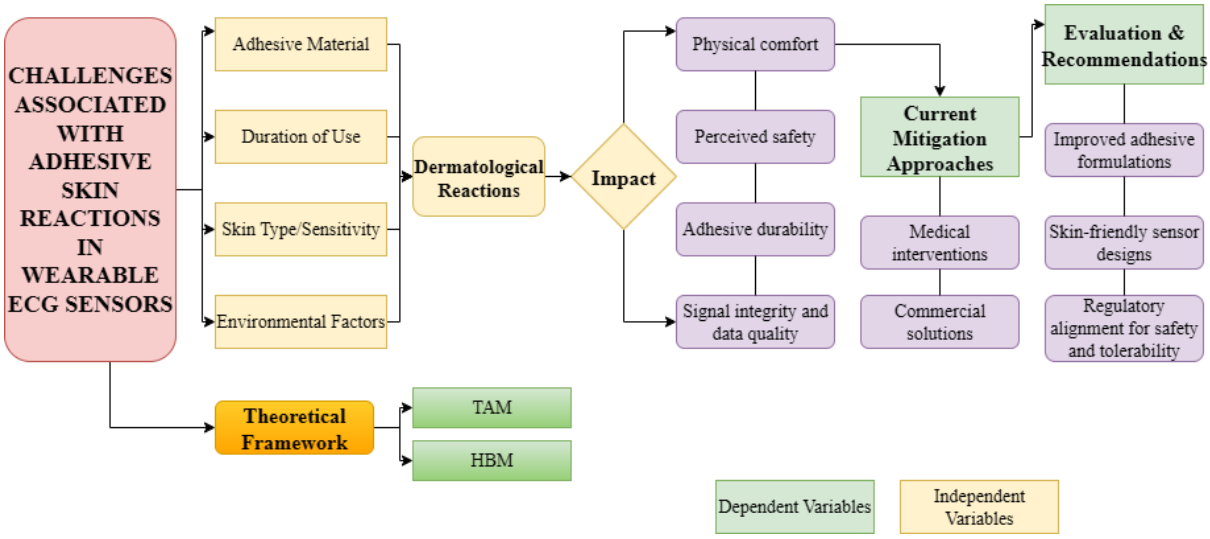

Figure 2.8: Conceptual Framework

2.12 Conclusion

Based on the above analysis, it has been concluded that wearable ECG devices have transformed cardiac monitoring; however, extended adhesion to the skin often results in dermatological complications. Biocompatibility, adhesion and signal quality vary among adhesives, hydrogels, silicones, acrylics and pressure-sensitive adhesives. Despite hydrogels having excellent conduction, they were subject to dehydration that irritated the skin and

caused signal issues. Moreover, acrylic has offered durability, but has caused allergic contact dermatitis. In addition to that, skin irritation, erythema, and allergies have compromised the comfort, signal integrity and long-term compliance of the user. In this way, commercial solutions were breathable, biocompatible materials and dry electrodes, while medical solutions were barrier creams, rotation of electrodes and corticosteroids. Further, regulatory requirements, such as the EU MDR, FDA clearances and compliance with the ISO 10993, were in place to protect patients and ensure performance. Therefore, in order to improve the effectiveness and acceptance of wearable ECG technologies, a trade-off needs to be achieved between adhesive performance, skin compatibility and regulation adherence.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Overview

The chapter introduces the appropriate research methods to gather the dataset and indicates methods with ethical ways to respond to the research appropriately. In this way, the application of Saunders' research onion uses that helps to identify suitable research methods and techniques to enhance research techniques. Research onion is a group of sequential layers of research methods; each layer is followed by another and determines the appropriate data collection and data analysis ***(Refer to Figure 10).*** Hence, the impact of Saunders' research onion has been facilitated for the identification of appropriate methods and techniques for the research.

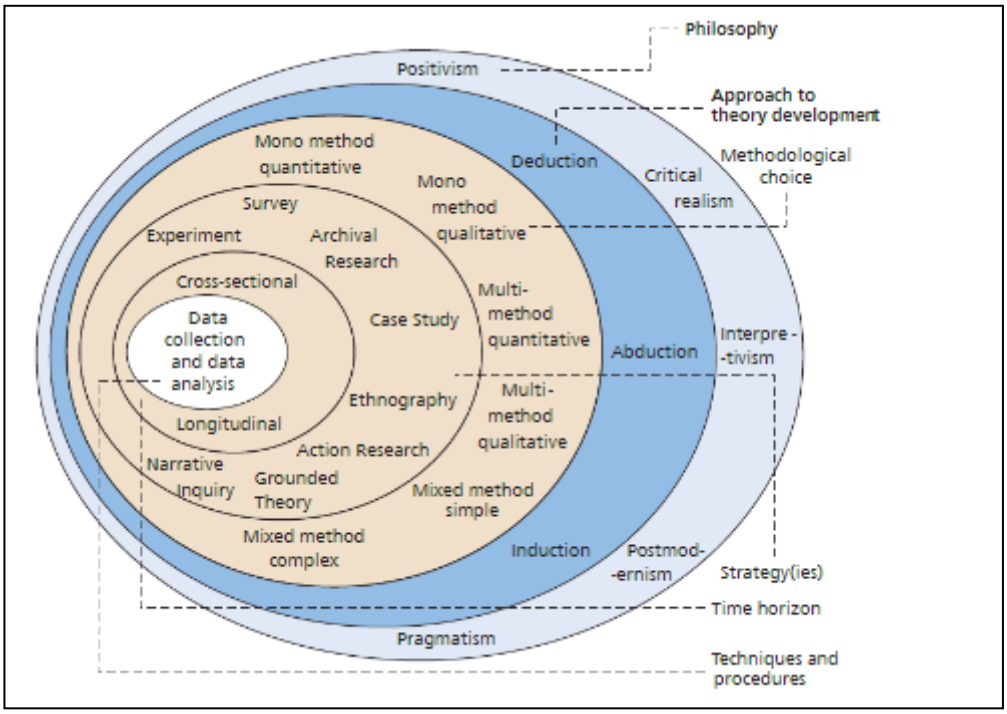

Figure 3.1: Saunders' research onion

(Source: Saunders *et al.*, 2019)

3.2 Research Philosophy

For this research, an interpretivism philosophy approach has been adopted for investigating the dermatological issues arising due to long-term use of wearable ECG sensors ***(Refer to Figure 11)***. An interpretivism philosophy was selected due to its focus on the context and subjective interpretation, attributes necessary to study user experiences and individual skin reactions. Interpretivism philosophy allows the researcher to interpret phenomena from the point of view of the subjects, providing a better understanding of the complexity of life

(Pervin and Mokhtar, 2022). This was particularly important in the present study, that focused on such problems as allergic reactions to adhesives, skin irritation or the influence of individual adhesive components on dermatological health. However, the positivism research philosophy has a limited ability to study human experience and behaviour in context (Blackwell, 2018). Apart from this, the positivism philosophy has not been selected and does not flexibility that is needed to model the subtle interrelation of the skin response of the user and the wearable.

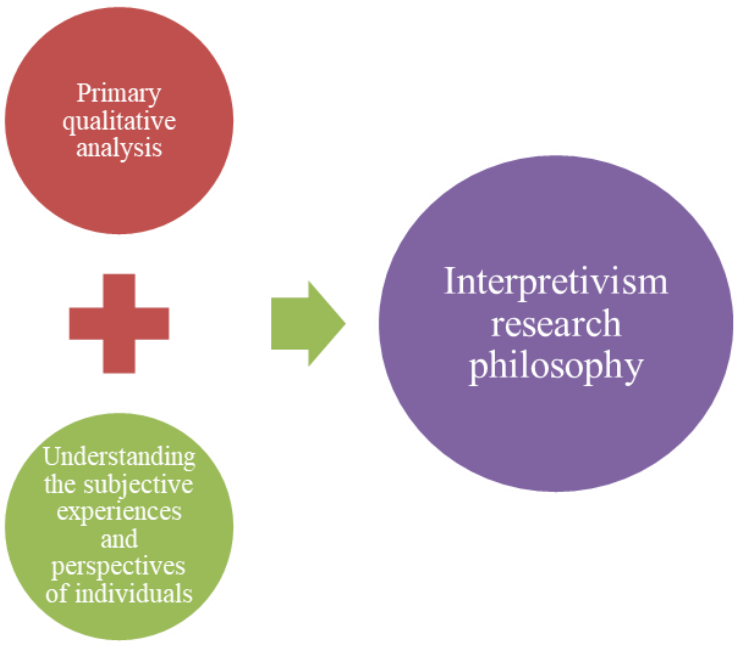

Figure 3.2: Research philosophy

(Source: Self-Developed)

Interpretivism philosophy has provided the opportunity to investigate ways skin differences and long-term continuous use affect the comfort, usability and quality of the signal of ECG monitoring. Accordingly, interpretivism research philosophy has supported the understanding of human behaviour in particular social as well as physiological settings (Žukauskas *et al.*, 2018). In this aspect, interpretivism philosophy in qualitative research of users' subjective interpretations and experiences with wearable ECG technologies. Thus, interpretivism has been more suitable for achieving the conceptualisation of skin-health and user-centred design within wearable ECG devices.

3.3 Research Approach

In this study, an inductive research method has been chosen to examine the dermatological issues associated with the long-term use of wearable ECG sensors ***(Refer to Figure 12)***. According to the inductive research approach, it is possible to develop new theoretical knowledge by delving into subjective experiences and by analysing them (Behal, 2023). This

research approach started with narrower observations about discomfort of the user, skin responses, and adhesive-related problems that further led to generalisations and concepts with a wider scope. On the other hand, deductive approaches are limited when the research has a preconceived hypothesis and resulting in researchers failing to identify inductively emerging themes (Kim, 2021). Based on this, the deductive approach was not suitable as it has limited flexibility and prevents research from exploring novel dermatological findings from real-world usage of wearable ECG sensors by users, and other aspects associated with it. In this way, the inductive approach has been taken in this study in order to correlate the single occurrences with general conclusions about skin safety and user satisfaction in regard to wearable ECG technologies.

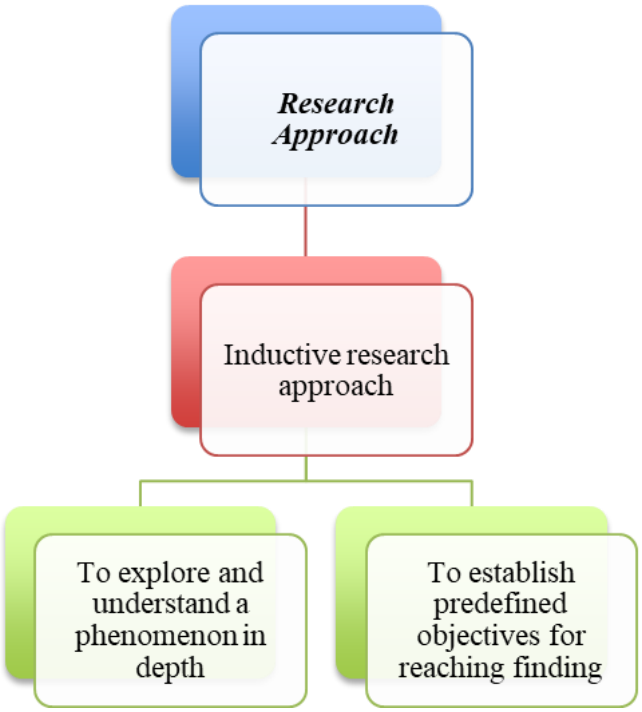

Figure 3.3: Research approach

(Source: Self-Developed)

A major weakness of an inductive approach is that it does not prove a theory but rather supports or disputes generalisations generated from prior data (Azungah, 2018). Nevertheless, inductive research approaches serve to uncover commonalities and new themes in the data, enabling a systematic interpretation of lived experiences (Naeem *et al.*, 2023). It has been well-suited for this research since the goal is to have an in-depth understanding of user experiences and emerging dermatologic problems without knowledge assumptions. The inductive approach has supported open-ended investigation on the effect of physical and chemical properties of ECG adhesives on adverse dermatologic reactions.

3.4 Research Strategy

In this research, a primary qualitative research strategy has been implemented to gain primary data on dermatological issues arising from long-term use of wearable ECG devices ***(Refer to Figure 13)***. Qualitative research strategy has emphasised non-numerical data and cites research in interpreting the subject matter based on personal experiences and perspectives (Lim, 2024). It has been stated that the primary qualitative strategy has been a flexible and open-ended strategy, particularly relevant to be able to investigate responses of individuals to adhesive materials and the consequences of prolonged skin contact. Moreover, this qualitative research strategy has promoted the study of skin-related issues due to the adhesive and the overall user experience reading comfort, durability and signal quality.

Figure 3.4: Research strategy

(Source: Self-Developed)

Secondary qualitative research strategy has limited availability, relevance and concerns about the quality of the data through the current weakness of the study that has decreased its transferability (Adu *et al.*, 2022). Due to these limitations, a secondary qualitative research strategy has not been selected that impacts research by restricting access to context-specific, up-to-date information needed to explore individual dermatological responses to the wearable ECG adhesive. Apart from this, primary qualitative data has enabled face-to-face contact with users and experts, so that practice obstacles and solutions to improving the dermatological safety and comfort have been developed by primary qualitative data. As such, the primary qualitative research strategy has been appropriate for this study because it aimed to capture an account of the primary investigation of expert explanations of the understanding of wearable ECG usage.

3.5 Sample Size Calculation

Purposive sampling has been considered most appreciated for the current study as it assisted in identifying the 8 participants, including medical technicians and biomedical engineers. This selection has been based on their job descriptions and a minimum of 2 years of experience working with the wearable ECG technology***(Refer to Figure 14)***. The purposive

sampling method has been pivotal for selecting cases that are information-rich from a larger population (Campbell *et al.*, 2020). From the same perspective, purposive sampling has been necessary for in-depth understanding since it permitted selecting the most important informants to the study (Tongco, 2017).As per the mono-method research choice, a telephone interview has been applied with the use of open-ended questions for the collection of the appropriate qualitative information from the select participants. In contrast, random sampling has limited effectiveness to ensure the representation of smaller or specific subgroups that resulting in under sampling of important viewpoints (Elfil and Negida, 2017). For these reasons, random sampling has not been applied in this study, because it overlooks the expertise targeted for effectively addressing dermatological issues. Thus, purposive sampling has been found appropriate in this research for the efficient collection of participants' opinions on dermatology difficulties related to weaning ECG sensors.

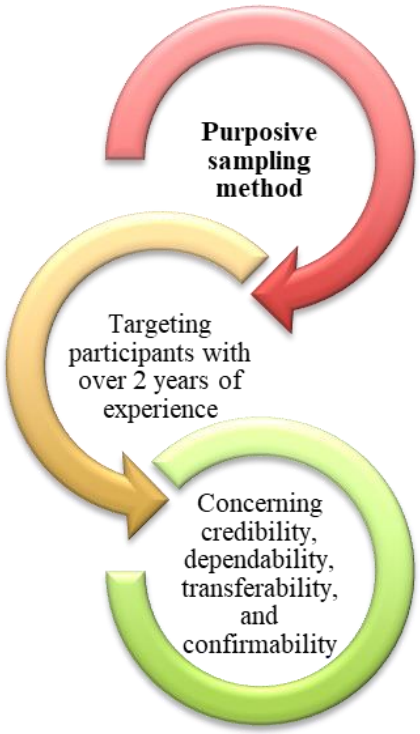

Figure 3.5: Research strategy

(Source: Self-Developed)

3.6 Data Collection Method

In this study, the primary data collection method (interview) has been chosen for this research to explore the dermatological challenges due to the extended use of wearable ECG sensors. Interviews as primary data collection techniques are especially appropriate as they enable the researcher to gather detailed information and expertise relevant to the research objectives

(Cheong *et al.*, 2023). The identified participants were invited to propose potential participants who can have related field experience and knowledge. This method has enabled the quality of the generated information in the output of the research. In this way, according to the consent, the telephonic interview had to be conducted to receive the necessary data, and the elaborated interview questionnaire did not include any personal questions, which may make the participant feel uncomfortable. Therefore, the participants were allowed to leave before the end of the interview according to their mindset. Moreover, this study employs thematic analysis to interpret the qualitative data obtained through telephone interviews. Thematic analysis offers a structured approach to examining textual information by identifying patterns, recurrent concepts, and overarching themes within the textual data. Through this process, it helps to generate deeper understanding of the data and capture insights relevant to the research focus (Erlingsson and Brysiewicz, 2017). The interview transcripts will be coded using NVivo software, which will assist in systematically identifying recurrent codes. These codes will be organised into broader categories and subsequently refined into overarching themes. This analytic process will enable the recognition of meaningful patterns within the data and ensure that the findings are closely aligned with the study's research objectives.

3.7 Time Horizon

The study has been performed in a cross-sectional time horizon to better evaluate the dermatological issues due to wearable ECG sensors over using time period***(Refer to Figure 15)***. The cross-sectional time horizon has facilitated implementation of the research within a particular timeline by adopting a rational course of action (Gupta *et al.*, 2021). Moreover, the cross-sectional time horizon is appropriate for the understanding and explanation of phenomena at a particular instant in time, taking a signal snapshot of the data (Maier *et al.*, 2023). In this aspect, the cross-sectional time horizon in data collection has been accomplished in an allocated time period. However, the longitudinal time horizon has required gathering data continuously over time, thus increasing the duration of the study and potentially decreasing the ability to meet project deadlines (Wood *et al.*, 2024). Therefore, the study has adopted a cross-sectional time horizon to gather qualitative data from users and experts in a particular period of time and analyse the current situation and problems associated with wearable ECG-included skin reactions.

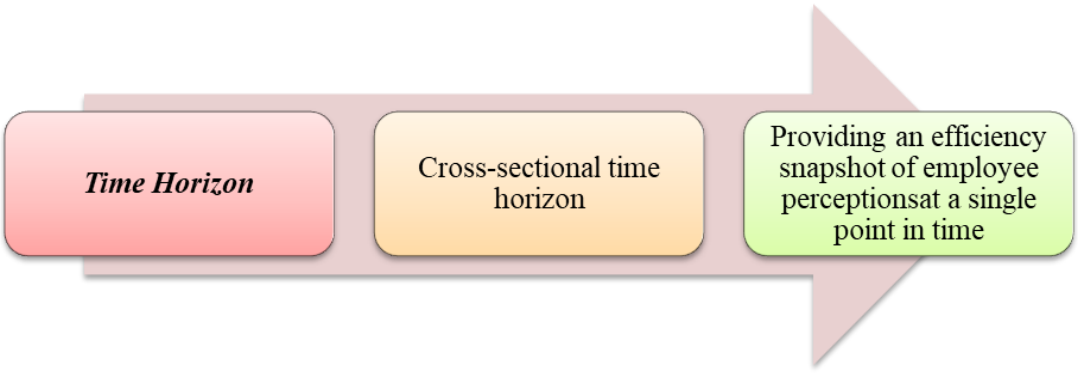

Figure 3.6: Time Horizon

(Source: Self-Developed)

3.8 Sources & Selection of Participants

Searching for potential interviews, there was a post onLinkedIn and through personal professional networks. The advertisement described the purpose and objectives of the study, as well as an email where people could respond if they were interested. In this study, a group of professionals (medical technicians and biomedical engineers) responded to the invitation, for which an information sheet and consent form were sent. These participants were chosen based on their specific job roles and a minimum of 2 years of hands-on experience working with wearable ECG technology. The goal was to get deep insights from the individuals most likely to provide useful, qualitative data on skin issues related to wearables. Within a week of the consent, each of the 8 selected participants was requested for a telephonic interview and asked 7 open-ended questions aimed at getting detailed feedback on skin reactions to the glue, comfort, and overall user experience. The interview protocol expressly included that the participation was voluntary and no personally sensitive data would be collected to supply personal, sensitive information, while pointing out their right to withdraw from the research at any time.A purposive sampling strategy was used to select 8 participants from medical technicians and biomedical engineers who provided informed consent for follow-up after one week. This selection aimed to achieve a balanced representation in terms of professional background, technical expertise with wearable ECG, gender, and years of experience with similar products. Participants were chosen based on their willingness to be contacted again and to share more in-depth insights about their experience. The choice of a smaller 8 participants, a diverse subgroup, the study sought to capture richer qualitative data without overextending participant burden and control the time required for conducting interviews and gathering meaningful information, in line with ethical guidelines.

3.9 Inclusion & Exclusion Criteria

Inclusion criteria	Exclusion criteria
Participants have been medical technicians or biomedical engineers	Individuals in unrelated job roles, including administrative staff, marketing professionals and others
Must have a minimum of 2 years of experience working with wearable ECG technology	Participants with less than 2 years of experience in this relevant field.
Must be fluent in English to ensure effective communication during the interview	Participants who are not fluent in English
Participants have actively worked in clinical or technical role involving ECG devices	Participants not currently working in roles involving wearable ECG devices
A telephonic 1:1 interview has been conducted	Group interviews have not been considered

Table 3.1: Inclusion and exclusion criteria

(Source: Self-Developed)

3.10 Ethical Considerations

This study has been conducted in line with theGDPR, and the University's ethical guidelines, data protection, and participant rights have been maintained.GDPRprovide provision for regulations of the processing of individual information in transparent manner (Carmi *et al.*, 2023). Prior to interviews, the researcher provided a consent form to the participants to read and sign, ensuring them the freedom to participate or withdraw within 10 days after data collection. Privacy has been protected by not collecting personal identifiers, and the data has been stored safely in encrypted cloud storage. All data will be wiped beyond recovery after usage. Ethical clearance was secured to be bound by legal and institutional norms, and to affirm the reliability, validity and trustworthiness of the study.

3.11 Conclusion

Based on the above methodology chapter analysis, the study has followed Saunders' research onion framework and obtained a primary qualitative method for exploring dermatological problems of weaning long-term wearable ECG sensors. This research has focused on subjective user experiences by following the interpretivism philosophy and inductive approach. Further, a primary qualitative research strategy and purposive sampling were used for obtaining a deeper understanding from participants. Moreover, telephonic interviews were conducted, and data were analysed by thematic analysis by following the 6 steps of Brawn

and Clark. Thus, the method has enabled a robust, reliable and context-based understanding of skin-related issues associated with wearable ECG technology.

CHAPTER 4: FINDINGS AND ANALYSIS

4.1 Introduction

This chapter presents the results of the qualitative study, analysing data collected from interviews with medical technicians and biomedical engineers regarding adhesive-related skin reactions in wearable ECG devices. This analysis followed Braun and Clarke's (2006)six-phase thematic approach, which provides a rigorous and systematic method for identifying and reporting recurring patterns within qualitative data. To ensure transparency and consistency, the transcripts were reviewed repeatedly, coded manually, and grouped into categories that were later refined into themes through iterative comparison and reflection.

The findings are organised into key themes that reflect participants' experiences of skin reactions, adhesive material performance, patient discomfort, workflow implications, design features, manufacturer responsibilities, and regulatory concerns. Direct quotations are used to illustrate these perspectives, while thematic charts and summary tables provide evidence of cross-case patterns and thematic prevalence. This integrated approach ensures that the voices of participants are represented faithfully while also demonstrating how these accounts converge or differ across professional roles and adhesive types.

4.2 Participants

Eight professionals participated in this study, comprising four medical technicians and four biomedical engineers. All had at least two years of experience working with wearable ECG monitoring devices, either in direct patient care or in technical development roles. This balanced composition allowed the study to capture both clinical and engineering perspectives on adhesive-related skin reactions.

Each participant was assigned a pseudonym (P1–P8) for confidentiality, with role and years of experience recorded to facilitate comparison across groups. Medical technicians generally emphasised patient-facing issues such as skin irritation and workflow disruptions, while biomedical engineers focused more on material properties, design solutions, and regulatory concerns. Table 4.1 provides an overview of the participants.

Participant	Role	Years of Experience
P1	Medical Technician	3
P2	Biomedical Engineer	5
P3	Medical Technician	4
P4	Medical Technician	2
P5	Biomedical Engineer	3
P6	Medical Technician	4
P7	Biomedical Engineer	6
P8	Biomedical Engineer	4

Table 4.1: Overview of Study Participants

(Source: Self Developed)

4.3 Thematic Analysis

The thematic analysis of the interview data, conducted manually and guided by Braun and Clarke's (2006)six-phase framework, generated six major themes:

1. Spectrum of Skin Reactions
2. Adhesive Material Trade-offs
3. Patient Discomfort and Workflow
4. Design Features
5. Manufacturer Improvements
6. Regulatory and Safety Considerations

These themes were developed through iterative coding of the transcripts, where meaningful data segments were identified, compared across participants, and clustered into broader categories. Repeated review of the transcripts allowed patterns to emerge, and cross-case analysis was used to highlight both convergences and contrasts between medical technicians and biomedical engineers. As shown in Braun and Clarke’s six steps of thematic analysis (Figure 4.1), the process moved from familiarisation with the data to defining and naming the final themes.

While technicians tended to emphasise direct patient-facing issues such as irritation, erythema, premature device removal, and the burden of repeated electrode application, engineers highlighted more technical and systemic aspects, including adhesive trade-offs,

design innovation, and regulatory compliance. Manual coding confirmed the prevalence of dermatological concerns across participants, while also revealing role-specific emphases: for instance, hydrogel maceration was raised by nearly all participants, whereas regulatory issues such as data protection and safety standards were raised primarily by engineers.

The findings presented in the following subsections therefore capture not only the **descriptive accounts of participants** but also demonstrate how thematic analysis provided a structured framework to integrate both **clinical realities and technical perspectives** in addressing the research objectives.

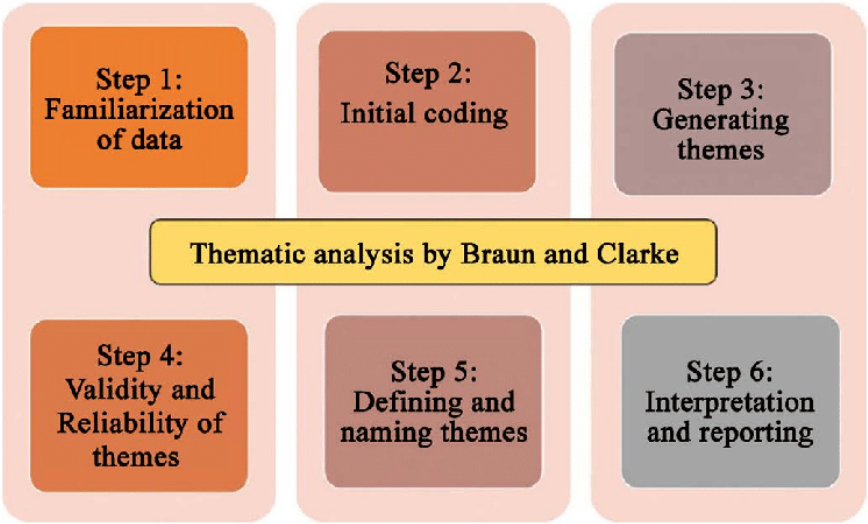

Figure 4.1: Braun & Clarke's Six steps of Thematic Analysis

(Source : (Braun and Clarke, 2006)

4.4 Themes and Codes

Theme	**Participant Quotes**	**Codes**
Spectrum of Skin Reactions	P1: "Patients tend to have irritation, skin allergies and peeling of skin, especially those with sensitive or elderly skin." P4: "Rashes and peeling led to premature discontinuation of patches." P5: "Hydrogels…associated with maceration."	• Erythema • Rash • Itching • Peeling • Maceration • Dermatitis • Blisters • Burning

Adhesive Materials Trade-off	P3: "Hydrogels give accurate ECG signals, but they dry up with time and leave the skin irritated." P4: "Acrylic adhesives are very sticky but can cause itching and red marks." P6: "Silicone is less irritant, but slips with activity."	• Hydrogel – good signal, dries/macerates • Acrylic – durable, irritant • Silicone – gentle, slips • Sweat resistance issues
Patient Discomfort & Workflow	P1: "When patients feel discomfort, they simply won't keep the device on." P4: "Rashes and peeling led to premature discontinuation… causing missed arrhythmias and repeat procedures." P3: "Patient's feedback is crucial for recognising adhesive skin reactions."	• Discomfort • Premature removal • Data gaps • Incomplete monitoring • Repeated applications • Increased workload • Observation/feedback practices
Design Features	P5: "Rounded, stretchable patches move with the skin and are less irritating." P6: "Soft silicone layers with breathable adhesives reduced redness." P2: "Mesh or vented backings avoid trapped sweat and heat."	• Mesh/breathable backing • Stretchable patches • Rounded patches • Soft silicone layers • Hydrogel-coated fabrics • Fractal conductive traces
Manufacturer Improvements	P6: "Biocompatible materials are necessary to avoid irritation and allow patients to complete monitoring comfortably." P5: "Barrier wipes before placement help to minimise damage."	• Biocompatible/hypoallergenic adhesives • Barrier wipes • Moderate/pressure-sensitive adhesives
Regulatory and safety Considerations	P1: "We always check IEC 60601-1 conformity before devices are used." P5: "FDA-approved devices showed better documentation on	• ISO 10993 • IEC 60601-1 • FDA approval vs EUA devices • HIPAA/GDPR compliance

	tolerance." P2: "Compliance with GDPR and HIPAA is necessary for remote monitoring systems."	

Table 4.2 : Themes and codes generated from interview transcript

(Source : Self developed)

4.4.1 Spectrum of Skin Reactions

The most consistent issue reported by participants was the presence of **skin reactions caused by adhesive electrodes**, which all eight interviewees recognized as a significant challenge in the use of wearable ECG devices. Described conditions included **itching, erythema, rashes, peeling, dermatitis, maceration, and blisters**, with the severity of these symptoms varying according to adhesive type and the duration of wear. Across accounts, three clear patterns emerged: hydrogels were often associated with maceration and skin softening, acrylics with irritation and hypersensitivity, and silicones with fewer allergic responses but problems of slippage or loss of adhesion.

Medical technicians generally highlighted the **visible and symptomatic effects on patients**, frequently noting discomfort severe enough to interrupt monitoring. One technician observed: *"Patients tend to have irritation, skin allergies and peeling of skin, especially those with sensitive or elderly skin"* (P1). Another explained: *"Rashes and peeling led to premature discontinuation of patches, causing missed arrhythmias and repeat procedures"* (P4). Biomedical engineers, on the other hand, tended to explain these reactions in terms of **material properties**, commenting on how hydrogels, while excellent for electrical conductivity, could trap moisture, or how silicones were skin-friendly but less durable during high movement. As one engineer stated: *"Hydrogels provide accurate ECG signals but are associated with maceration when moisture accumulates"* (P5). Another added: *"Silicones are generally non-allergic, but they lose grip over time and may slip during motion"* (P2).

Cross Analysis: Taken together, these accounts show that dermatological complications are both a **patient comfort issue** and a **design/material challenge**. Technicians emphasized the **clinical consequences**, such as discomfort and early device removal, while engineers underscored the **biophysical mechanisms** behind skin responses. This dual perspective illustrates how skin reactions not only affect patients' willingness to continue wearing ECG

patches but also impact the reliability of monitoring, making adhesive choice a critical factor in balancing comfort and performance.

4.4.2 Adhesive Material Trade-offs

The type of adhesive emerged as a central factor influencing both skin tolerance and the overall performance of wearable ECG devices. Participants consistently described a tension between achieving strong electrode adhesion and minimising dermatological reactions. Three materials were most frequently discussed: **hydrogels, acrylics, and silicones**, each associated with distinct advantages and drawbacks. Hydrogels were valued for their high conductivity and stable signals but criticized for causing **maceration** when moisture accumulated and for **drying out** during prolonged use. As one participant explained: *"Hydrogels give accurate ECG signals, but they dry up with time and leave the skin soft and irritated"* (P3). Acrylic adhesives were praised for durability and sweat resistance, but they were also strongly associated with **rashes and hypersensitivity reactions**. A technician remarked: *"Acrylic adhesives are very sticky indeed, but they can cause itching and red marks on the skin"* (P4). By contrast, silicone adhesives were described as **gentle and hypoallergenic**, reducing the likelihood of irritation, though several participants noted they often failed to maintain adhesion during extended monitoring or with increased movement. An engineer explained: *"Silicone is less irritant and easily removed, but it tends to slip off with activity or perspiration"* (P6).

Cross-analysis: While both groups acknowledged the strengths and weaknesses of each adhesive type, their emphases differed. Medical technicians highlighted the **practical consequences for patients**, particularly the discomfort caused by acrylics and the premature removal linked to hydrogel reactions. Biomedical engineers, meanwhile, framed their accounts in terms of **material trade-offs**, stressing how conductivity, durability, and biocompatibility must be balanced. This contrast underscores the central challenge of adhesive development: finding solutions that ensure **clinical effectiveness** while safeguarding **skin health and patient comfort**.

4.4.3 Patient Discomfort & Workflow

Another recurring theme across the interviews was the impact of patient discomfort on both compliance and clinical workflow. Participants explained that **skin irritation often led to premature removal of ECG patches**, interrupting the monitoring process and creating gaps

in data collection. In some cases, patients chose to remove devices earlier than recommended due to persistent itching, burning, or peeling, which ultimately undermined the effectiveness of long-term monitoring. As one technician explained: *"Rashes and peeling led to premature discontinuation of patches, causing missed arrhythmias and repeat procedures"* (P4). Another observed: *"When patients feel discomfort, they simply won't keep the device on, even if it is important for diagnosis"* (P1).

The consequences of early removal were not limited to patient experience but extended to **workflow inefficiency and data reliability**. Medical staff often had to reapply electrodes or repeat procedures, which increased workload and delayed results. Engineers also emphasised the technical implications of interrupted monitoring, pointing out that lost data reduced the continuity of signals and in some cases compromised diagnostic accuracy. One engineer commented: *"Removal of devices too early hurts long-term signal integrity and creates fragmented data sets"* (P5). Another noted: *"Repeated application is not just uncomfortable for the patient, it also adds to material costs and staff time"* (P7). Participants also described how patient discomfort was commonly identified through visual checks, patient feedback, or observation after electrode removal, with these monitoring practices often confirming the irritation that ultimately led to premature device discontinuation.

Cross-analysis: Technicians framed discomfort primarily as a **compliance problem**, describing how patient reactions and premature removal disrupted everyday monitoring and increased the need for repeated interventions. Engineers, on the other hand, highlighted the **broader technical and system-level consequences**, such as data gaps, reduced diagnostic reliability, and added costs. Together, these perspectives show that patient discomfort is not only a clinical concern but also a **systemic issue**, directly influencing both the efficiency of workflows and the validity of the monitoring process.

4.4.5 Design Features

Participants also highlighted several **design features** of wearable ECG patches that could reduce adverse skin reactions while maintaining effective signal quality. Among the most commonly mentioned were **breathable or mesh backings**, which were seen as helping to reduce moisture build-up and skin maceration; **stretchable or rounded patches**, which were thought to minimise friction and improve comfort during movement; and **soft silicone layers or fabric-based coatings**, which could provide a gentler interface with the skin. Some

participants also discussed emerging innovations such as **hydrogel-coated fabrics** and **fractal conductive traces**, which offer both skin-friendliness and stable conductivity. A technician explained: *"Rounded, stretchable patches move with the skin and are less irritating for patients who need to wear them for longer periods"* (P5). Another emphasised: *"Soft silicone layers with breathable adhesives reduced redness and peeling in sensitive patients"* (P6). Similarly, an engineer observed: *"Mesh or vented backings avoid trapped sweat and heat, which are common causes of skin irritation"* (P2).

Cross-analysis: Technicians placed greater emphasis on design features that directly improved **patient comfort**, such as stretchable patches and breathable layers, while engineers more frequently focused on **novel material innovations** like hydrogel-coated fabrics and conductive fractal designs. Together, these perspectives highlight that design features function as a bridge between **clinical usability** and **engineering innovation**, showing that incremental improvements in form and material choice can significantly reduce dermatological complications without sacrificing device performance.

4.4.5 Manufacturer Improvement

Participants consistently stressed the role of manufacturers in reducing adhesive-related skin complications through improvements in materials and application practices. A key expectation was the development of **biocompatible and hypoallergenic adhesives** that minimise allergic responses while maintaining reliable adhesion. Several interviewees also suggested the use of **barrier wipes or pre-application treatments** to create a protective layer between the skin and adhesive, thereby reducing direct irritation. In addition, some participants advocated for **moderately adhesive, pressure-sensitive options** that could be safely applied to patients with fragile or aged skin without causing damage during removal. A technician stated: *"Biocompatible materials are necessary to avoid irritation and allow patients to complete monitoring comfortably"* (P6). Another participant explained: *"Barrier wipes before placement help to minimise damage, especially for patients with sensitive skin"* (P5).

Cross-analysis: Medical technicians primarily focused on practical improvements that could be implemented during routine use, such as pre-application skin protection and gentler adhesives for vulnerable patients. Biomedical engineers, however, framed their responses around **upstream innovations**, emphasizing the need for material research, rigorous testing,

and integration of biocompatibility standards into design pipelines. This dual emphasis demonstrates that manufacturer improvements are essential not only for **patient safety and comfort** but also for ensuring **long-term compliance and trust in wearable ECG technology**.

4.4.6 Regulatory and Safety Considerations

Participants also emphasized the importance of regulatory oversight in ensuring the safe and effective use of wearable ECG adhesives. Several noted that standards such as **ISO 10993 for biocompatibility** and **IEC 60601-1 for medical electrical equipment** were critical benchmarks that adhesives and devices must satisfy before clinical use. Others highlighted the role of **national and international regulators**, including the **U.S. Food and Drug Administration (FDA)** and emergency use authorizations (EUAs), in determining product approval and post-market surveillance. Privacy and data protection frameworks, such as **GDPR** in Europe and **HIPAA** in the United States, were also raised as essential considerations in remote monitoring, given the sensitive nature of patient health data. As one participant explained: *"We always check IEC 60601-1 conformity before devices are used, because safety cannot be compromised"* (P1). Another added: *"FDA-approved devices showed better documentation on tolerance and adverse effects compared to those under emergency authorizations"* (P5). Engineers, in particular, also stressed the importance of data security, with one stating: *"Compliance with GDPR and HIPAA is necessary, not just for the device but for the whole monitoring system"* (P2).

Cross-analysis: While both groups acknowledged the significance of regulation, technicians generally framed it in terms of **compliance during practice**—ensuring that devices used in their clinics met required safety standards. Engineers, on the other hand, emphasised the **broader regulatory environment**, including design requirements, international differences in approval processes, and data protection mandates. Taken together, these perspectives underline that regulatory concerns extend beyond paperwork; they are integral to ensuring **patient safety, clinical reliability, and public confidence** in wearable ECG technologies.

4.5 Findings Summary

The analysis across eight participants revealed that adhesive-related dermatological complications remain a **persistent and multifaceted problem** in wearable ECG monitoring.

The most dominant concern was **skin reactions**, commonly reported, which ranged from erythema, itching, and peeling to more severe dermatitis and blistering. These reactions were linked directly to the type of adhesive used, with **hydrogels** associated with maceration and drying, **acrylics** with irritation and hypersensitivity, and **silicones** viewed as gentler but prone to slippage during prolonged use.

The consequences of these reactions were profound, influencing both **patient tolerance and clinical workflow**. Discomfort frequently led to premature removal of patches, incomplete datasets, repeated applications, and delayed diagnosis. For technicians, this translated into added workload and inefficiencies, while engineers saw the risk of compromised data integrity and diagnostic accuracy.

Participants also pointed to **design features** as opportunities for improvement. Comfort-oriented solutions such as breathable mesh, stretchable or rounded edges, and soft silicone layers were discussed, alongside material innovations like hydrogel-coated fabrics and fractal conductive traces. Complementary to design, **manufacturer improvements** were seen as essential. These included the development of hypoallergenic, biocompatible adhesives, the provision of barrier wipes, and gentler pressure-sensitive adhesives for fragile or elderly patients.

Finally, **regulatory oversight** was regarded as crucial for ensuring device safety and public trust. While technicians emphasised compliance with day-to-day clinical safety standards such as IEC 60601-1, engineers highlighted broader frameworks including ISO 10993 for biocompatibility, FDA approvals, and data protection under GDPR and HIPAA.

Overall, the findings reveal that adhesive complications are not only a matter of **patient comfort** but also of **system performance and regulatory accountability**. The study demonstrates that addressing this issue requires integrating clinical perspectives with engineering solutions, ensuring that future devices are safe, effective, and acceptable to patients.

The cross-analysis highlighted clear patterns between professional roles. **Technicians consistently reported patient-facing concerns**, such as irritation, peeling, and premature removal, which they linked to discomfort and increased clinical workload. In contrast, **engineers emphasised material trade-offs, design innovations, and regulatory**

frameworks, reflecting their focus on device development and compliance. Despite these differences, both groups unanimously identified **skin reactions and adhesive materials** as the most critical concerns. The clustered bar chart (Figure 4.2) illustrates these patterns, showing that while every participant raised issues of skin reactions and adhesives, themes such as manufacturer improvements and regulatory concerns were more commonly highlighted by engineers than by technicians. Figure 4.3 shows the frequency of each theme mentioned by participants, with skin reactions and adhesive materials reported by all eight, while themes such as design features and manufacturer improvements were noted less often, indicating variation in emphasis across experiences.

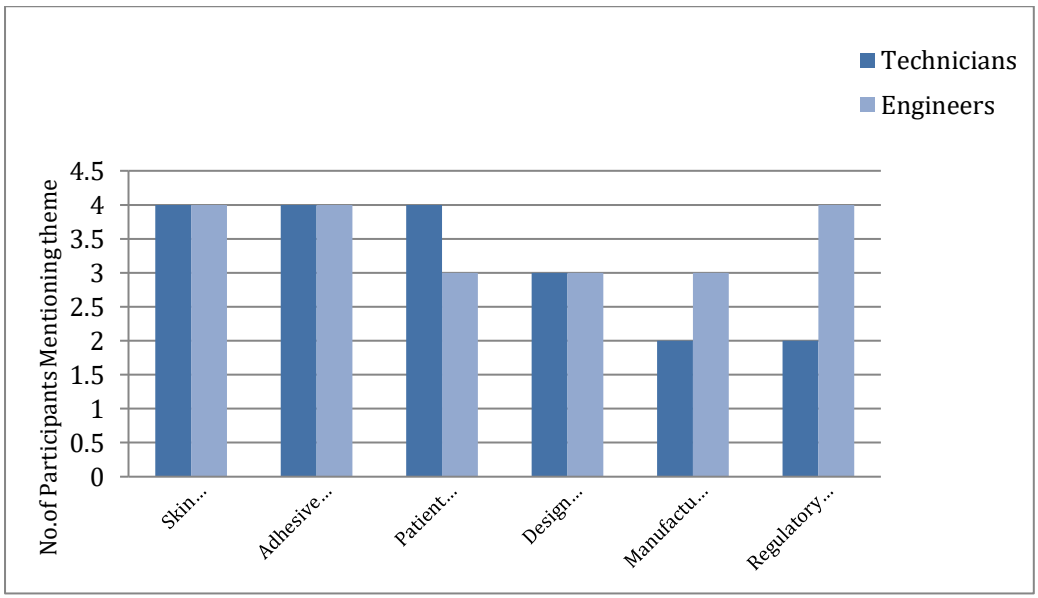

Figure 4.2: Cross-Analysis of Themes by Professional Role

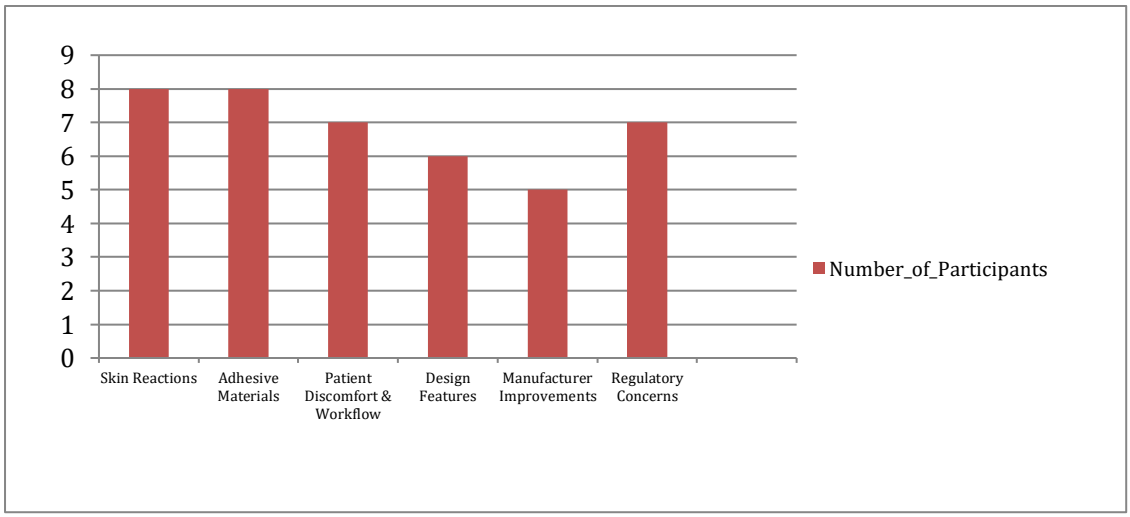

Figure 4.3 Theme prevalence across all participants

(Source : Self developed)

Theme	Key Findings from This Study	Result/Outcome
Spectrum of Skin Reactions	Common issue: erythema, itching, rashes, peeling, dermatitis, maceration, blisters.	Adhesive type is the main trigger: hydrogels = moisture/maceration acrylics = irritation silicones = slippage.
Adhesive Materials Trade-off	Clear trade-offs between signal quality and skin tolerance.	No single adhesive is ideal; choice involves balancing diagnostic accuracy with dermatological safety.
Patient Discomfort & Workflow	Discomfort caused premature patch removal, leading to data gaps, repeat procedures, and added workload.	Patient adherence and workflow efficiency are directly undermined by skin-related complications.
Design Features	Breathable mesh, stretchable/rounded edges, soft silicone, hydrogel-coated fabrics, fractal conductive traces suggested.	Innovative design features can reduce irritation while maintaining electrode performance.
Manufacturer Improvements	Demand for hypoallergenic and biocompatible adhesives; calls for barrier wipes and moderate-strength adhesives.	Manufacturers play a crucial role in minimising complications through safer materials and user support tools.
Regulatory Concerns	Importance of ISO 10993, IEC 60601-1, FDA approvals; recognition of GDPR/HIPAA in remote monitoring.	Regulatory vigilance ensures patient safety, device reliability, and trust in wearable monitoring technologies.

Table 4.3 Summary of Key Findings

(Source : Self developed)

4.6 Discussion

4.6.1 Dermatological issues (allergic and irritant skin reactions) for extensive use of wearable ECGs

Chronic use of wearable ECG devices has been associated with several dermatological complications that compromise user comfort and monitoring accuracy. According to existing

literature, typical adhesive reactions comprise an irritant contact dermatitis, erythema, itching, burning and scale, frequently aggravated by the type of adhesive and duration of use (Kwon *et al.*, 2021; Yao *et al.*, 2022). Moreover, hydrogels, despite their widespread use of conductivity, were found to cause moisture-induced maceration, while acrylic adhesives resulted in redness, stiffness and sensitivity (Bashir *et al.*, 2020; Dahiya *et al.*, 2024b). Accordingly, from the interview findings, itching, burning, sensations, rashes, erythema and peeling of the skin are common dermatological issues for extensive use of wearable ECGs. Further, dermatological problems related to wearable health devices are usually eczematous rashes with allergic contact dermatitis that areunderdiagnosed despite the prolonged skin contact in glucose monitors, activity trackers, and other wearables (Khatsenko *et al.*, 2020). The development of blisters and skin maceration was emphasised, particularly below hydrogel adhesives that retain moisture and impair the skin barrier. Further found allergic contact dermatitis that resulted in severe erythema, pustules and hypersensitivity after prolonged wear, occurring more frequently in the elderly or more sensitive patients.

Based on the literature analysis, silicone adhesives have been reported as skin-friendly, low allergenic for sensitive skin, but do not have strong adhesion in highly active periods (Lee *et al.*, 2017; Liu *et al.*, 2017). This aligns with the findings, which revealed that the majority of participants tolerated silicone adhesives with less irritation and were well tolerated, but consistently reported premature removal when moving or monitoring for longer periods. Similar results found in another study, where the combined usage of silicon adhesives with grade tapes resulted in lower risk of skin allergywith good biocompatibility properties(Kang *et al.*, 2024). This suggests that silicone has been a safer alternative for comfort; however, technological changes are necessary to improve adhesion and maintain compatibility with the skin. The most common and distressing types of skin conditions are the allergic and irritant reactions such as dermatitis, erythema, maceration and peeling. These repeated issues illustrate the pressing need for adhesive revisions that achieve a trade-off between consistent monitoring and dermatological safety;*thus, objective 1 has been achieved successfully.*

4.6.2 Role of adhesive composition and physical characteristics in triggering adverse skin responses during prolonged skin contact

Adhesive composition and physical characteristics played a crucial role leading to negative skin sensitivity responses after long-term skin attachment for wearable ECG monitoring. From the existing literature, hydrogel is popular due to their conductivity however, they have led to maceration and erythema due to moisture entrapment, particularly in humid regions (Bilić, 2018). Findings from participants support this, as hydrogel adhesives were associated

with irritation, skin breakdown and discomfort while worn continuously. It has been found that despite the increased reliability of the signal provided by the hydrogels, its contribution to the disruption of the skin barrier underscores the need for breathable or moisture-wicking modifications. Accordingly, adhesive composition and materials skin long-term exposure, such as hydrogel, acrylic, silicone and pressure sensitivity, have caused dermatological problems that depend on their mechanical and chemical characteristics (Fialho *et al.*, 2024). Further, from existing literature, despite the strengths and resistance of the acrylic glues to sweat, redness, hypersensitivity and delayed allergic contact dermatitis were common findings related to this type of adhesive (Tramontana *et al.*, 2023). Based on the participant findings, rashes, peeling and dermatitis form acrylic while used long-term. It has been stated that although acrylic ensures durability and stable ECG signals, its aggressive adherence is not compatible with old or sensitive skin, necessitating safer alternatives, including medical silicones. Similarly, in the literacy analysis, silicone adhesives have been reported to be skin-friendly and less allergenic (Dyson *et al.*, 2023). As per the findings, it also stated that silicone adhesives were less irritating and generally well-tolerated, but their lower adhesion frequently promoted premature patch removal that partly interrupted serial ECG monitoring and compromised long-term data reliability. This signifies that silicone adhesives have provided an improved solution, but their sweat and motion stability also need to be improved through new designs. Therefore, the content of adhesive ingredients, physical properties, including tackiness, moisture permeability, breathability, from the adhesive composition of adhesive fabric relate to the degree of skin irritation to skin, *thus objective 2 has been met successfully.*

4.6.3 Impact of skin-related side effects affects user experience, comfort, adhesive durability, and ECG signal quality

Skin-related side effects from ECG electrodes commonly include irritation, redness, or dryness from adhesive and gel, thereby negatively impacting user experience as it causes discomfort and potential skin damage. The study findings have emerged across skin reaction, adhesive materials, patient experience and preventive approaches. Thus, the majority ofskin reactions reported were irritant contact dermatitis, erythema, itching, burning, rashes, peeling and blisters. Excessive or improper application of glues in ECG devices has been associated with dermatological complications (Yang *et al.*, 2024). Further, adhesives like hydrogel adhesives were associated with moisture-induced maceration, whereas acrylic adhesives frequently resulted in hypersensitivity, redness and dermatitis during long-term usage. Each of the adhesives with long-term skin contact through wearable ECG devices has been

associated with significant dermatological risks, particularly in relation to monitoring prolonged periods of time (Mao *et al.*, 2023). For instance, biosensors printed directly on skin use an adhesive to stick such sensors and thereby which causes skin damage (Albert, 2020). Therefore, it can be stated that the study findings have been in line with the existing literature regarding the impact of adhesive utilised in ECG devices on skin and overall quality of health monitoring. Further, it has been found that allergic contact dermatitis was reported to be characterised by pustules and severe itching and irritation, especially in patients with sensitive or thin skin. Micro-abrasion due to repeated application and retraction contributes to the risk of localised inflammation and infections (Tinoco *et al.*, 2025). Hydrogel adhesives were advantageous in terms of conductivity, causing maceration, especially in warm and humid climates (Bilić, 2018). It has been found that discomfort leads to early device removal or non-resolution of application, resulting in monitoring interruption, disaggregated datasets and loss of important arrhythmia signals in some instances. It indicates suboptimal compliance, and higher time consumption has added extra burden to clinical workflow as alternative or multiple attempts for adhesive were frequently necessary. Additionally, hydration loss from the hydrogel matrix during the first 24 hours has been identified as the primary cause of adhesive breakdown against leaved skin susceptible to irritation and microbial penetration (Norahan *et al.*, 2023). Thus, current findings in line with existing literature and adhesive have been more susceptible to irritation and microbial penetration, and this has been more pronounced with the physically active users or sensitive skin. Therefore, it can be stated that adhesives have negatively impacted user comfort, and multiple attempts at maintenance have added to the burden in clinical workflow, thereby hampering the quality of ECG signal data for monitoring. Thereby effective understanding of the impact of adhesives on ECG devices successfully meets the third objective.

4.6.4 Commercial and medical approaches to prevent skin irritation in wearable ECG technologies

Commercial and medical strategies to prevent skin irritation from ECG devices focus on using dry, flexible electrodes made with biocompatible materials like silk, carbon nanotubes and hydrogels. It has been found that several commercial and medical approaches were identified that contribute in preventing irritation. According to Ma *et al.* (2024), commercial utilisation of skin-friendly electrodes like epidermal electrode engineering with electrospinning method helps with mitigation of skin reactions. Further, it has been found that regular skin assessments, patient feedback, post-removal examinations electrodes site rotations and occlusive barriers films. Similarly, Pullano *et al.* (2022), have explored the use

of dry electrodes, offering promising solutions helping to mitigate skin irritation that has led to common issues with traditional wet electrodes, by eliminating the need for skin preparation like gel applications. Further, it has been found that manufacturers were advised to consider the use of biocompatible, hypoallergenic and moisture-impervious materials and pressure-sensitive adhesive to minimise skin irritation that allows for effective monitoring. Further, Pullano *et al.* (2022), explored the use of dry electrodes as promising solutions for the mitigation of skin irritation by eliminating the need for skin preparation for gel applications, which has been a common issue with traditional wet electrodes. For instance, an elastic belt that presses the electrodes and dielectric barrier to the skin offers the best option to obtain good quality signals (Nigusse *et al.*, 2021). Thus, it can be stated that current findings slightly differ from existing studies as current literature focuses on skin preparation to avoid skin irritation, whereas study insights point towards use of biocompatible, hypoallergenic and moisture-impervious materials usage for minimizing skin irritation. It has been found that dermatological problems remain most common and debilitating and use of novel adhesive agents and anticipatory monitoring plants remain essential aspects. According to Rauf *et al.* (2024), use of biocompatible adhesive creates soft adhesives, thereby making it easier to release from skin and make ECG electrodes gentler on skin than typical commercial devices. Further, Xiao *et al.* (2021), explored that regular changing of electrode placement, allows for avoiding irritation and effective skin recovery. Thus, current findings were in line with existing literature as both indicate novel use of adhesive for avoiding skin irritation. Therefore, regular changing ECG placement, novel adhesive helped to understand commercial and medical approaches required for preventing skin irritation in wearable ECG technologies.

4.6.5 Recommendations for adhesive materials and wearable designs for better safety and tolerability of long-term ECG monitoring

Further improvement in the adhesive materials and designs of the wearables is needed to ensure the long-term, safety of these devices, skin compatibility and patent tolerance of the wearable ECG monitoring. According to existing literature, hydrogel adhesives have excellent conductivity but tend to dry, get macerated and become more irritating in humid or active settings (Kim *et al.*, 2022). The results also demonstrated common complaints of dermatitis, itching and redness, under long duration of use with hydrogels. This indicated the need for breathable and sweat-wicking composition. In this aspect, ISO 100993 biocompatibility standards have improved patient tolerance while ensuring regulatory safety (Sharma and Luthra, 2023). Similarly, results found that strict protocols to ISO 10993 and

fresh ECG adhesives have become an important issue and clinical recommendation, and have been determined by understanding compliance to FDA regulations regarding data tolerance. Further, based on literacy analysis, acrylic adhesives were strong and sweat resistant, but were often implicated in redness, hypersensitivity and delayed allergic contact dermatitis (Tramontana *et al.*, 2023). This was supported by the patient experience that acrylics induced a rash, peeling and dermatitis during long-term use. It has been found that although acrylic improved durability and stability of ECG signals, their excessively strong adhesiveness leaves much to be designed for aged or sensitive skin, necessitating safe replacement alternatives, such as medical-grade silicones.

As per existing literature, the use of the post-market surveillance (PMS) suggested by the FDA and EU MDR to ensure transparency to manufacturers about the chemical nature of adhesives and gels with high skin irritation (Pane *et al.*, 2019). Similarly, regular advice, including FDA PMS has played an essential role in early identification of such adverse events and to respond quickly (Raj *et al.*, 2019). As such, PMS is an efficient regulatory policy tool to provide a robust control over quality manufacturing practices in order to minimize the risk of skin irritancy. In addition, devices of the future need to be compatible with IEC 60601-1 safety standards to confirm unchanged functionality in addition to skin protection (Grob *et al.*, 2015). Similarly, from the findings, it has been found that device makers have done well to incorporate the Health Insurance Portability and Accountability Act (HIPAA) and GDPR compliant data treatment in the design of ECG as well, with wearables and personal health data seen as one and the same in remote monitoring. Therefore, FDA, ISO 10993, IEC 60601, HIPAA and GDPR frameworks with biocompatible adhesives and breathable wearable designs have enhanced skin safety, data quality and long-term patient adherence, thus objective 5 has been met successfully.

4.7 Summary

Based on the above discussion, it can be stated that adhesive used in ECG devices and prolonged usage lead to dermatological challenges. Skin reactions, adhesive materials, experience and preventive approaches have been major concerns. Utilization of breathable mesh layers and micro-vented design have enhanced airflow and adhesives kept the patch to move with skin, preventing friction and peeling. Further, it has been discussed that design features have the potential to minimize irritants and improve long-term usability.

What this study adds is the **dual perspective**: technicians focused on the visible discomfort experienced by patients, while engineers explained the biological mechanisms of irritation in relation to material properties. This highlights that dermatological outcomes are not only a **clinical safety issue** but also a **design trade-off** rooted in material science. Therefore, commercial and medical approaches in adhesive design or preparing skin for such application needs proper compliance with regulatory guidelines.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study set out to examine adhesive-related skin reactions associated with wearable ECG devices, drawing on the perspectives of both medical technicians and biomedical engineers. Using Braun and Clarke's six-phase thematic analysis, six overarching themes were identified: the spectrum of skin reactions, adhesive material trade-offs, patient discomfort and workflow challenges, design features, manufacturer responsibilities, and regulatory and safety considerations. Together, these themes provide a comprehensive view of the multifaceted challenges that adhesives create in the long-term use of wearable ECGs.

The findings confirmed that dermatological complications are the most consistent and distressing outcomes of ECG adhesive use. Participants described skin problems ranging from mild erythema and itching to severe dermatitis, blistering, and maceration. Hydrogels were associated with moisture-related breakdown, acrylics with hypersensitivity and rashes, while silicones were more skin-friendly but prone to premature detachment. These issues were not only sources of patient discomfort but also disrupted clinical workflows, leading to premature removal of devices, incomplete data, and repeated procedures. Importantly, the findings highlighted differences in perspective between the two professional groups: technicians emphasised patient-facing challenges and workflow burden, while engineers focused on the material properties of adhesives and the regulatory frameworks guiding product safety.

Overall, the study demonstrates that adhesive-related skin reactions are not trivial side effects but central barriers to the safe, tolerable, and reliable use of wearable ECG technology. Addressing them requires collaborative efforts between clinicians, engineers, manufacturers, and regulators to create solutions that balance dermatological safety with clinical effectiveness.

5.2 Implications of the Study

The findings of this research hold several important implications for clinical practice, biomedical engineering, regulatory oversight, and the broader field of wearable health technologies. Collectively, the results highlight that adhesive-related skin reactions are not minor inconveniences but significant barriers to effective cardiac monitoring. They affect not

only patient comfort and safety but also the reliability of data, clinical workflow efficiency, and the long-term adoption of wearable ECG devices.

5.2.1 Clinical Implications

From a clinical perspective, dermatological complications caused by adhesives undermine both patient adherence and monitoring accuracy. The study revealed that skin irritation often leads to premature device removal, incomplete data, and repeated application procedures, thereby creating additional burden for medical staff. This aligns with previous evidence that dermatological discomfort is one of the most common reasons for discontinuation of wearable monitoring. For clinicians, this underscores the need for proactive skin assessment and management protocols. Regular monitoring of electrode sites, educating patients about early signs of irritation, and adopting strategies such as site rotation or barrier film use are necessary to prevent escalation of dermatological issues. More importantly, clinicians should consider tailoring adhesive selection based on patient-specific factors such as skin sensitivity, age, and activity levels, thereby balancing tolerability with data integrity.

5.2.2 Technical Implications

For biomedical engineers, the study has significant implications regarding adhesive formulation and device design. The results emphasised that no single adhesive provides the ideal balance between skin compatibility and signal reliability. Hydrogels ensure conductivity but promote maceration; acrylics provide durability but cause hypersensitivity; while silicones are gentler but prone to detachment during movement or sweating. These findings point to the urgent need for material innovation that integrates biocompatibility, breathability, moisture control, and sufficient adhesion for long-term wear. Engineers must therefore adopt a user-centred approach that accounts not only for technical performance but also for the lived experiences of patients and clinicians. Additionally, integrating flexible and breathable design features—such as mesh backings, stretchable patches, and hypoallergenic formulations—could mitigate dermatological risks while maintaining signal quality.

5.2.3 Regulatory Implications

The study also carries regulatory implications, as skin reactions raise important questions about product safety, accountability, and trust. Findings highlighted that technicians rely

heavily on devices meeting safety benchmarks such as IEC 60601-1, while engineers emphasised ISO 10993 biocompatibility testing, FDA approval processes, and data protection frameworks like GDPR and HIPAA. These results demonstrate that regulatory oversight plays a pivotal role in maintaining both clinical safety and public trust. Stronger enforcement of these standards is necessary to ensure that adhesives are rigorously tested for dermatological safety before they reach the market. In addition, transparent post-market surveillance systems would allow manufacturers and regulators to identify adverse reactions promptly and intervene effectively.

5.3 Limitations

While the study generated valuable insights, several limitations must be acknowledged. The sample size was relatively small, with only eight participants, which restricts the generalisability of the findings. A larger participant pool may have captured a wider range of experiences and perspectives. The participant group was also limited to medical technicians and biomedical engineers. Although this provided a useful balance between clinical and technical viewpoints, the exclusion of patients meant that direct user experiences were not captured.

Recruiting ECG users presented particular challenges. Ethical considerations related to patient vulnerability, privacy, and informed consent made it difficult to involve end-users directly in the study. Furthermore, wearable ECG users often represent a diverse group—including elderly patients and those with underlying cardiac conditions—making access and engagement more complex. As a result, the study relied on professional accounts rather than patient perspectives, which may limit the depth of understanding of personal experiences with skin irritation and device tolerability.

Another limitation arises from the reliance on self-reported accounts from professionals. Their narratives may be influenced by recall bias, selective memory, or professional framing of events. In addition, the study was context-specific, focusing exclusively on ECG adhesives, and therefore the findings may not be fully transferable to other wearable health devices such as glucose monitors or activity trackers. Despite these limitations, the study offers important insights into adhesive-related complications and provides a foundation for future research.

5.4 Recommendations

The findings of this study point to several key recommendations for improving the safety and tolerability of wearable ECG adhesives. For clinical practice, there is a need for structured skin monitoring protocols that ensure early detection of irritation and provide timely intervention. Educating patients about common skin reactions and encouraging them to report discomfort early can help reduce premature device removal. Clinicians should also tailor adhesive selection to individual patients, taking into account factors such as age, skin sensitivity, and activity levels.

For manufacturers, the development of safer and more biocompatible adhesives should be a priority. Incorporating breathable, sweat-wicking designs and transparent labelling of adhesive ingredients would empower clinicians to make informed choices for their patients. Manufacturers should also establish stronger post-market surveillance systems to capture reports of adverse skin reactions and respond with product improvements in a timely manner.

Regulators play a critical role in safeguarding patient safety. Stricter enforcement of ISO and IEC standards, alongside stronger oversight of data privacy compliance, is essential to ensure that devices are both physically safe and ethically responsible. International harmonisation of these standards would also reduce variability in product safety across regions and support global adoption of best practices.

5.5 Future Research

Future research should build upon this study by incorporating broader and more diverse participant groups, including patients who have direct experience with adhesive-related complications. Patient-centred trials would provide a richer understanding of tolerability across different age groups, skin types, and health conditions. Comparative testing of hydrogel, acrylic, silicone, and emerging smart adhesives under controlled conditions could generate empirical evidence about their dermatological effects and trade-offs in signal quality.

Longitudinal studies are also needed to examine the cumulative impact of adhesives during extended monitoring, as short-term trials may underestimate long-term complications.

Research into innovative materials, such as nanomaterials, self-healing adhesives, and conductive fabrics, may hold the key to achieving both comfort and reliability. In addition, economic analyses are warranted to estimate the costs of adhesive-related complications in terms of disrupted workflows, repeated procedures, and reduced patient adherence.

5.6 Closing Statement

In conclusion, this study demonstrates that adhesive-related skin reactions are a central challenge to the success of wearable ECG monitoring. Dermatological complications compromise patient comfort, disrupt clinical workflows, and undermine data integrity. Addressing these challenges requires an integrated approach that combines clinical vigilance, engineering innovation, manufacturer accountability, and regulatory enforcement. By prioritising patient safety, comfort, and long-term adherence, wearable ECG devices can better realise their potential to transform cardiac monitoring and improve health outcomes.

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Appendices

Appendix 1: Interview Transcripts

Participant 01

(0:03 - 2:16)

Good morning, how are you? Can you introduce yourself to us? Hi, good morning. I'm good. I hope you're also doing well.

I'm a medical technician. Oh, that's good. Okay.

Shall I start the interview? Oh, yes, please. Okay. My first question is, based on your clinical or technical knowledge, what skin reaction have you seen from wearable ECG monitoring continuously? Oh, well, I noticed especially with patients of patches over, you know, over a few hours, like maybe like more than 24 hours.

Patients tend to like irritation, skin allergies and all. And also, like mostly I've seen in elderly patients, you know, as you know, they have fragile skin and easily breakable skin also. So it can lead to small blisters and also skin peels and everything.

These reactions are like more frequent with allergic allergies, especially the skin is not properly cleaned or in humid environments. Okay, that's good. So my next question is, how do you evaluate or monitor for adhesive related skin reaction in ECG monitoring patient? Oh, yeah.

Well, I have, I believe the regular visual checks, you know, you have to monitor the skin and the ECG, you know, the sites we have to monitor that. It does make us alert of any potential early signs of any redness or irritation or itchiness or anything like that. I usually check the skin for any skin peel or any redness, like any signs of swelling, rashes during the replacement and ask about any itchy or discomfort if patient feel.

(2:18 - 2:59)

Okay, that's good. Okay, coming to my next question. Based on a technical knowledge, how do different adhesive materials impact both skin compatibility and ECG signal quality? Yes, wearable ECG devices are like generally made with different types of, you know, different types of different adhesive materials in there, like such as hydrogels, acrylics, silicons, and I think conductive fabrics and also like pressure sensitive adhesives.

(3:00 - 3:26)

These are the characteristics, these characteristics are affected by material used. And also like across these materials, hydrogel are the best for the short term, you know, for short term use and for the signal clarity. And also like silicons are most gentle and suited for, you know, the long term or low motion applications like.

(3:27 - 4:25)

Yeah, that's a good answer. And my next question is, have patients reported any discomfort or discontinued usage due to skin reaction? And how does this affect your clinical workflow or device performance? Oh, that's a good question. Like, yes, the answer is yes.

And many patients complain about the, you know, difficulty or discomfort because of these, like redness or itchiness, especially with the hydrogel or acrylic adhesives. And however,

many of these people stop wearing this device early, so we only get a short amount of data. And alsoresulting these holes of ECG monitoring and time lost wasting of reapply electrodes or I try to try other more gentle alternatives which slows down the process, you know.

(4:27 - 5:45)
OK, thank you. My next question is, have you seen any design features operational for wearable ECG sensors to make your skin safe or have you implemented them in a device? Oh, yes, I have used silicone layers, you know, mesh backing or breathable adhesives such as design features. These materials, you know, have reduced the risk of accumulating these threads and aggravation.

And also, like, you know, such as sensitive skins that makes them more appropriate, you know, for the for the long term ECG monitoring, especially in old age people like elderly people and alsohigh risk patients. Oh, that's great. My next question is, how would manufacturers improve the sensor design or material to prevent skin irritation on wearable ECG sensors? I think, you know, as per my understanding, silicone or soft hydrogel manufacturers can can use medical grade silicone or they can use hypoallergenic adhesives based on specific needs.

(5:46 - 7:01)
You know, these adhesives provide long, long lasting and also like redness free, no pee sacrament or like or for external ECG wear. So it is safe to use. Yeah, that's a good answer.

And my last question for you is, in your professional practice, have there been any regulatory concern or skin reaction safety notification associated with these devices? Yeah, look, in my medical knowledge, in medical technician's knowledge, and as a medical technician, I always check if a device is compliant with IEC knowledge. Sorry, the complaint with IEC 60601, one standard before using it for recording skin contact ECG data. You know, this standard is key for safety and also for especially in the areas of insulation and the patient contact.

Thank you so much for your valuable time.

Participant 02

(0:03 - 0:17)
Good morning, how are you? I am good, how are you? I am good. So, can you please introduce yourself to me? Yeah, of course. I am a biomedical engineer with five year experience.

(0:18 - 0:29)
Okay, that's great. So, shall I start the interview? Yeah, of course. Okay, before that please be aware that this interview is now being recorded.

(0:30 - 3:41)
So, the first question for you, based on a clinical or technical knowledge, what skin reaction have you seen from wearable ECG monitoring continuously? Well, in field trials with silicone-based ECG adhesives, subjects reported fewer reactions than the acolytes, but some still experience skin pull and dryness. Okay, so the next question, how do you evaluate or monitor for adhesive-related skin reaction in ECG monitoring patients? I have felt that skin testing in the lab was a good way to work out whether adhesives have the potential to irritate.

We usually apply patches with the skin, evaluate this for redness, bumps, or any other allergic reaction to quality skin.

Okay, that's good. So, the next question for you, based on your technical knowledge, how do different adhesive materials impact both skin compatibility and ECG signal quality? Well, from my experience, silicones are skin-friendly, non-allergic, and over time they lose their grip. Moreover, pressure-sensitive adhesives are quickly applied but can be more of an issue for those with sensitive skin.

Yet, hydrogel gives better initial adhesion and signal quality, making it the perfect choice for a quicker, firmer, oily experience. Oh, that's great. So, the next question for you, how patients reported any discomfort or discontinued usage due to the skin reaction, and how does this affect your clinical workflow or device performance? You know, most of the time I have faced this problem.

Most of the users discontinued ECG wearable due to irritation, especially during the long-term use. They have led to higher device returns and calls for adaptation of both cases. It makes trying new things take longer and messes with signal integrity, leading to further skin-friendly material tests, and trying other adhesive strategies.

Oh, okay. So, the next question, have you seen any design features operational for wearable ECG sensors to make your skin safe, or have you implemented them in a device? Of course, yes. Structurable and round-shaped ECG patches or fracture conductive tracers have an evolving design that molds into the movement of your body, clearing the needs of any tension or friction on the skin.

(3:42 - 5:39)
When combined with the biocompatible adhesives, they increase patient comfort and reduce irritation in the clinical and home environments. That's great. So, the next question, how would manufacturers improve the sensor design or material to prevent skin irritation on wearable ECG sensors? I think incorporating mesh packing or micro-vented design into the patch structure can improve air circulation beneath the adhesive.

This can increase sweating and skin maceration, particularly in warm or moist climates. Skin-friendly breathable patches allows for up to several days of continuous monitoring with ECG devices. Okay.

So, your final question in this interview, in your professional practice, have there been any regulatory concerns or skin reaction safety notifications associated with these devices? As for biomedical engineering, the growing role of software and data in ECG devices, I have provided complaints to patient safety, patient safety standards, as well as cyber security or privacy regulation, such as Health Insurance Portability and Accountability Act and GDPR during remote monitoring and data transfer to secure the patient's information. That's really nice. Okay.

Thank you for your valuable time and your information. Thank you so much. Thank you.

You are always welcome. Thank you.

Participant 03

(0:03 - 0:27)
Good morning, how are you? Can you please introduce yourself to me? Yeah, I'm great. Thanks for asking. I'm a medical technician working with VWCG and patient monitoring system daily.

Okay, that's good. Oh, shall I start the interview? Yeah, go ahead. Okay, this interview is being recorded.

(0:28 - 4:11)
And my first question is, based on your clinical or technical knowledge, what skin reaction have you seen from wearable ECG monitoring continuously? After the ECG patch removal, patients frequently comment on itching or burning sensations. There has been a few cases where the rash ventures outside of that electrode area. The reactions are more common in those with the sensitive skin and generally appear within one or two days of uninterrupted use.

Okay, my next question is, how do you evaluate or monitor for adhesive skin reactions in ECG monitoring patients? Yeah, so my understanding is that patient's feedback is very crucial for adhesive skin reactions in ECG monitoring patients. I always inquire about their discomfort, itching, burns as well. As observed, adhesive areas are for any redness, dryness or blisters, especially in elderly patients.

And those who are worn, they make long term with sensitive skin. Okay, thank you. My next question, based on your technical knowledge, how do different adhesive material impact both skin compatibility and ECG signal quality? Okay, so as per my knowledge, hydrogels give accurate ECG signals and they dry up with time as well, which is a desirable adjustment in long term use.

While on the other hand, the alkylics remain stable when one is sweating and most of the time the alkylic causes irritation to the skin and reuse of connective fabric is possible with a decrease in signal quality. So, hydrogels are the most suitable gels in a clinical ECG when there is a minimal motion. Okay, my next question, have patients reported any discomfort or discontinued usage due to skin reactions? And how does this affect your clinical workflow or device performance? Yeah, skin reactions, especially among old patients or diabetics.

It's very common and they are likely to take out the monitors when discomfort sets in. So, this interrupts the seamless tracking and compels us to restart the session and making the procedure a nightmare. Both the patient and the patients.

Now, we play skin types. Okay, very good answer. So, my next question, have you seen any design features operational for wearable ECG sensors to make your skin safe or have you implemented them in a device? Okay, so, as per my knowledge, one of its key features is mesh backing for efficient airflow.

(4:12 - 6:04)
It allows the patch to breathe and reduces skin issues like rashes or migrations from trapped moistures under the patch. This is a design difference we have experienced better comfort

with, especially in patients who sit small or live in hot and humid environments. Okay, that's a good answer.

So, my next question to you is, how would manufacturers improve the sensor's design or material to prevent skin irritation on wearable ECG sensors? Okay, so, I believe in hypoallergenic adhesives like silicon and adding weak materials to the wear area. The adhesives are gentle, particularly for aged or diabetic sufferers and breathable backing layers reduce set buildup and migrations. These have been able to wear for a longer without skin issues.

Okay, now I see that. Okay. My last question for you is, in your professional practice, have there been any regulatory concern or skin reaction safety notification associated with these devices? So, the main challenge is to sidestep biocompatibility, showing that the device can be in contact safely with the sensitive skin for like an extended period of time.

(6:05 - 6:33)
Based on the risk and complexity of the intervention, my organization needs to follow strict international quality standards such as ISO 10993 with regulatory guidance from entities like FDA. Okay, thank you so much for your valuable time. This is a nice talking with you.

Yeah, yeah. Thank you.

Participant 04

(0:03 - 0:20)
Hi, good morning. How are you? Can you please introduce yourself to me? Hello, good morning. I'm doing well, thank you.

I recently have been working as a medical technician. Oh, that's great. So, shall I start the interview? Sure, sure, sure, sure.

(0:21 - 1:33)
Okay, before that, please be aware that this interview is now being recorded, okay? Yeah, sure, definitely. Okay, my first question for you, based on your clinical or technical knowledge, what skin reactions have you seen from wearable ECG monitoring continuously? I believe that a lot of skin breakdown and maceration is experienced, you know, particularly when patches are not used rotationally and the adhesives makes the skin moist and weakened. In some cases, it leads on removing the patch and hydrogel adhesives are more likely to aggravate this by retaining excess moisture.

Okay, that's good. So, how do you evaluate or monitor for adhesive-related skin reactions in ECG monitoring patients? I have found that interchanging electrode positions and some type of battery films before application has helped decrease reactions. So, therefore, I always pay attention to the adhesive applied areas and advise as many skin rest periods in between to avoid irritation.

(1:35 - 4:55)
Okay, so the next question, based on your technical knowledge, okay, how do different adhesive materials impact both skin compatibility and ECG signal quality? As per my understanding, while hydrogels provide clean signals, they are non-adherent when dry and

acrylic adhesives are very sticky indeed but can cause rubbing or itchiness and red marks. Although they do not cause skin pain, the silicone adhesives are easily removed and might slip off when a user is moving around heavily. As a result, acrylic is best for active patients who require durability.

Okay, so the next question, have patients reported any discomfort or discontinued usage due to skin reactions and how does this affect your clinical workflow or device performance? Yes, rashes and skin peeling have led to premature discontinuation of ECG patches. This often leads to garbage data or arrhythmia misses and this means that our clinical team has to pre-perform procedures resulting in a loss of time in addition to demotivating patients concerning digital monitoring tools. Okay, so have you seen any design features operational for wearable ECG sensors to make your skin safe or have you implemented them in a device? I think hydrogel coated fabrics are most suitable for skin that sticks gently without damaging the skin and the material could be glued directly to human skin without significant irritation and it was easily peeled off without harming the skin.

Okay, that's a good answer. So, the next question, how would manufacturers improve the sensor design or material to prevent skin irritation on wearable ECG sensors? Breathable mesh layers allow airflow and help avoid rashes or sweating under the patch and patients report less irritation when they use patches with vented backing. So, it may be a minor design change but it makes the vehicle much more comfortable.

Okay, really. So, the last question for you, in your professional practice, have there been any regulatory concern or skin reaction safety notification associated with these devices? In my personal experience, I've seen redness of the skin with long-term use of patches like BiosenseFlexwear that prompted me to verify that they had obtained their IEC 60601 certification and it turned out that in some cases contact surface and insulation safety norms were not satisfied. Okay, that's good.

Thank you for your valuable time and your information. Thank you. Thank you for giving this opportunity to talk with you.

Yeah. Yeah, thank you so much and this is the end of this interview. Okay, thank you.

(4:55 - 4:55)
Bye-bye.

Participant 05

(0:03 - 4:43)
Hi, good afternoon, how are you? Hi, good afternoon, I'm doing well, how are you? I'm good. Okay, can you please introduce yourself to me? Yeah, sure. Hello, I'm a biomedical engineer with three years of experience in wearable medical devices.

Okay, that's good. Okay, shall I start the interview? Yeah, please, sure. Okay, so please be aware that this interview is now being recorded, okay? Yeah, I'm fine.

Okay, my first question for you, based on your clinical or technical knowledge, what skin reaction have you seen from wearable ECT monitoring continuously? Based on my clinical or technological knowledge, skin maceration takes place beneath skin adhesives that possess

a propensity to maintain moisture, most commonly hydrogels. This reduced skin barrier can cause or exacerbate erythema, irritation and potential minor lacerations requiring patch reapplication. So, motion-induced friction exacerbates these negative effects and it consequently compromises device usability, thus hindering patient adherence.

Yep, that's it. Okay, okay, so the next question for you, how do you evaluate or monitor for adhesive-related skin reaction in ECT monitoring patients? All right, actually, I have noticed that the process in skin-friendly designs begins with testing various adhesives on different skin types to check for reaction, comfort and durability. This is done to prevent materials used in the fabrication of the mask from causing allergies and so that there is no irritation and also helps in the comfort of wearing the mask over long durations.

Okay, that's a good answer. So, the next question, based on your technical knowledge, how do different adhesives material impact both skin compatibility and ECG signal quality? Well, based on my technical knowledge, while hydrogel adhesives have high signal quality, they dry out fast and especially with prolonged usage and sweat, so the ability to adhere in wet conditions is offered by acrylic adhesives, but however, they tend to irritate the skin. Skin-friendly silicone-based adhesives that are also reusable, but may slip.

So, that's why silicone applications work wonders for sensitive skin in the long run. Oh, really? Okay, so the next question, how patients reported any discomfort or discontinued usage due to skin reaction and how does this affect your clinical workflow or device performance? Oh, that's an interesting question. So, adhesive-related discomfort is a common factor leading to patient non-compliance, especially in humid settings.

So, lastly, removal of the device too early will also hurt the long-term signal integrity and this results in incomplete data sets and poor reviews of the device performance in clinical studies. So, as of now, we are now testing breathable and reusable alternatives. Okay, that's good.

Next is, have you seen any design features operational for wearable ECG sensors to make your skin safe or have you implemented them in a device? Yeah, that's an interesting question. Yes, sure. As a biomedical engineer, I have implemented rounded, stretchable ECG patches that move with skin.

It's designed most perfectly around curved body parts that prevent peeling or redness. And after days of long-term use, patients describe the patch as smoother and less irritating. Yeah.

(4:44 - 6:24)
Okay. So, the next question, how would manufacturers improve the sensor design or material to prevent the skin irritation on wearable ECG sensors? So, to talk about this, I think the formula of skin-friendly patches is a breathable mesh, a low-irritant adhesive, as well as a flexible backing. Patients experience less inflammation and irritation when these designs are implemented.

In addition, changing patch location, every application and using barrier wipes before placement all help minimise skin damage during extended ECG monitoring. Yeah. Okay, thank you.

And this is your final question. All right. In your professional practise, have there been any regulatory concerns or skin reaction safety notifications associated with these devices? So, in

my professional practise, some of the devices used were EUA approved and hence did not have full biocompatibility testing I have seen higher rates of complaints, especially from sensitive users.

Since that time, we have trended towards strictly using those that are fully FDA approved due to better tolerance data given by the skin. Yeah. Okay.

Thank you so much for your valuable information and your time. You're very welcome. No problem.

Thank you.

Participant 06

(0:03 - 5:10)
Hi, good afternoon. How are you? Hi, I'm good. How are you? I'm good.

Okay, can you please introduce yourself to me? I'm a medical technician with four years of experience in ECG monitoring and patient coordination. Okay, that's good. So, shall I start the interview? Yeah, sure.

Yeah, we can go ahead. Okay. Please be aware that this interview is now being recorded, okay? Okay, yeah.

My first question, based on your clinical or technical knowledge, what skin reaction have you seen from wearable ECG monitoring continuously? Where I'm treated, allergic reaction, allergic contact dermatitis is usual in a long-term wearing of ECGs. It causes the development of small bumps and unbearable discomfort in some patients and this normally happens when one carries out like continuous use of same type of adhesives and the condition get worsens as long as there is no period of restoration to the skin. Okay, my next question, how do you evaluate or monitor for adhesive related skin reaction in ECG monitoring patients? I feel that the most effective method in monitoring after the adhesive removal is to critically observe the proximity to look at the indications of inflammation marks or any abrasions that can point to a reaction.

Any skin reaction can recur among patients are also noted in the records. Okay, that a good answer. Okay, the next question to you, based on your technical knowledge, how do different adhesive material impact both skin compatibility and ECG signal quality? In my technical knowledge, actually silicone adhesives are often, they do not leave a sticky residue behind.

They seem to be relatively safe for the elderly community. In high activity, they slip and move the electrodes causing signal artifacts. These are more for like home monitoring than high motion environments.

Okay, the next question, how patients reported any discomfort or discontinued usage due to skin reactions and how does this affect your clinical workflow or device performance? Patients frequently discontinue due to hydrogen breakdown and sweating. This has already caused multiple signals to fail within 24 hours. In clinical practice, it delays the treatment decisions and in research, it can cause like increased amount of dropout rates.

At this time, your priority is in better adhesion and comfort in future designs. Okay, that's good. So, the next question, have you seen any design features operational for wearable ECG sensors to make your skin safe or have you implemented them in a device? Yeah, I have used soft silicone layers with breathable adhesives in the ECG devices.

This actually prevents wetting of the skin and lessens the irritation when used on longer occasion. Patients said that they feel more comfortable and noted less redness, particularly in the patients with the sensitive or like age type of skin. Okay, the next question, how would manufacturers improve the sensor design or material to prevent skin irritation on wearable ECG sensors? From my understanding, before developing the ECG monitors, the use of biocompatible materials is necessary to avoid any irritation on the skin as well.

It should be moisture wicking material so that the skin could breathe properly. Okay, that's nice. So, my final question to you, in your professional practice, have there been any regulatory concerns or skin reactions, safety notification associated with these devices? Sure, we had few challenges, mainly in terms of skin breakdown among the older adults.

(5:11 - 5:34)
Our facility has now achieved new stringent protocols requiring dialing down the confirmation related to conformity regarding ISO 10993 and IEC 606011 before any use of fresh ECG adhesives. Okay, thank you. Thank you for your valuable time.

(5:35 - 5:38)
No worries. Have a good time with you. Thank you so much.

Thank you.

Participant 07

(0:03 - 0:25)
Hi, good afternoon, how are you? Can you please introduce yourself to me? Good afternoon, I am well today. Currently, I am working as a biomedical engineer. Okay, that's good.

Shall I start the interview? Yeah, sure. Okay, please be aware that this interview is now being recorded. Okay.

(0:26 - 1:02)
My first question for you, based on your clinical or technical knowledge, what skin reaction have you seen from wearable ECG monitoring continuously? Okay, I have shown a lot of irritant contact dermatitis in our trials, particularly with the hydrogel or acrylic adhesives over an extended period. So, this shown up as a red scaly patches with small lesions. These are more common when electrodes are put in high sweat regions or reused without being repositioned.

(1:04 - 2:17)
Okay, that's good. My second question for you, how do you evaluate or monitor for adhesive skin reactions in ECG monitoring patients? Okay, I think, yeah, the materials are supporting contact with clean and dry skin. I have made the patches that stay in place and breathe well.

Moreover, the factors such as skin type, temperature and daily activities were all taken into accountin order to prevent common issues such as peeling and rashes. Okay, that's a good answer. The next question, based on your technical knowledge, how do different adhesive materials impact both skin compatibility and ECG signal quality? Okay, yeah, acrylic adhesives have good adhesions and are sweat resistant.

So, they may be a good choice for ECGs for long duration. But this can be irritating on older skin or inflammated skin. Mostly, I have seen the patients develop rashes after 48 hours.

(2:18 - 3:32)
They are powerful but not the skin friendly as well, especially for sensitive users. Oh, I see. Okay, next question, have patients reported any discomfort or discontinued usage due to skin reaction and how does this affect your clinical workflow or device performance? Of course, the allergies and discomfort top the list of reasons wearables get rejected post ECG test.

Okay, this impact workflow efficiency as terms must find, order and use a more suitable adhesive. Long term studies are particularly affected as many drop out and those who remain show the signal in modulated differentially during activities. Okay, next question, have you seen any design features operational for wearable ECG sensors to make your skin safe or have you implemented them in a device? No, I could not find any special protection projection that covered the skin.

(3:33 - 5:25)
In order to date, a majority of device use the conventional adhesive such as hydrogel or acrylic which can become irritating. We typically must pay extensive amount of attention to skin and rod patches frequently. Okay, the rod patches.

Okay, the next question, how would manufacturers improve the sensor design or material to prevent the skin reaction on wearable ECG sensors? Okay, in my knowledge like the incorporating pressure sensitive instead of strong and aggressive adhesive will allow for a moderate level of bonding without toxicity. This make it able to be easily removed from the skin without causing any tearing of the skin and is particularly useful for fragile or geriatric skin. This can reduce the surface adhesion but still guarantees the continuous monitoring of ECG.

Okay, that's a good answer from you. So, my final question for you, in your professional practise, have there been any regulatory concerns or skin reactions, safety notification associated with these devices? Yes, some ECG patches raise the patient safety red flags under IEC 606011. Since there were report of skin irritation, particularly with the acrylic adhesives, we informed the manufacturers and made the appropriate filings under ISO 10993 for testing on skin compatibility and FDA post market surveillance guidance.

Yeah, that's it. Okay, thank you. Thank you so much.

(5:26 - 5:29)
Thank you for your valuable time. Yeah, thank you.

Participant 08

(0:03 - 4:21)

Hi, good morning, how are you? Good morning, I'm good, how are you? I'm good. So, can you please introduce yourself to me? Yeah, sure. I'm a biomedical engineering specialist focusing on wearable ECG device development.

Okay, that's great actually. So, shall I start the interview? Yeah. Okay.

So, this interview is now being recorded, okay? Okay. So, my first question is, based on your clinical or technical knowledge, what skin reaction have you seen from wearable ECG monitoring continuously? In terms of technical reasons, skin reactions are mainly the result of constant occlusion and moisture. We have observed erythema and mild ulceration beneath hydrogel-based electrodes with conventional use.

So, material stiffness as well as poor breathability, if you have a certain degree of passion in the segregation site, it's generally easier to stimulate. Okay, that's good. So, the next question, how do you evaluate or monitor for adhesive-related skin reaction in ECG monitoring patients? Well, I have seen a lot of responses for poor deployment.

In this way, I have always recommended dry skin before use, a secure fitting and using adhesive that matches the user's skin type. These processes have helped reduce friction, moisture buildup, and any skin damage. Okay.

So, the next question, based on your technical knowledge, how do different adhesive material impact both skin compatibility and ECG signal quality? From my perspective, though hydrogels have a good signal conductivity because of the moisture provided by them, but wearing it for long durations can cause skin maceration. After this dry out, signal strength degrades rapidly. Accordingly, hydrogel would be a good choice only for short-time monitoring as it is not suitable for application to sweaty or humid conditions.

Okay. So, next question, how patients reported any discomfort or discontinued usage due to skin reaction and how does this affect your clinical workflow or device performance? Basically, long wear of the adhesive can cause painful skin rotation in some patients. When they remove the device early, we lose crucial data points and it delays diagnosis, especially for remote monitoring and necessitate additional clinic visits to resolve the concern or repair.

Oh, that's great. Yeah. So, have you seen any design features operational for wearable ECG sensors to make your skin safe or have you implemented them in a device? Yes, I have seen conductive traces in the form of fractal shapes that conform to stretching, thus minimizing strain.

They are used with biocompatible adhesives, giving better contact and hold that is strong without causing any of the common skin issues of itching, rash or tearing. Okay. So, the next question for you, how would manufacturers improve the sensor design or material to prevent skin irritation on wearable ECG sensors? First of all, avoid irritation by requesting hypoallergenic adhesives, breathable mesh backings as well as flexible materials when designing a device, including skin barrier films, patch rotation and testing over a range of skin types may also enhance both comfort as well as improve signal stability to support long-term ECG monitoring.

(4:22 - 4:48)

Okay. So, your final question for me. In your professional practice, have there been any regulatory concerns or skin reaction safety notification associated with these devices? In my professional practice, biocompatibility remains a significant regulatory concern.

(4:49 - 5:16)
ISO 10993 and FDA guidance put a lot of emphasis on comprehensive testing to ensure that materials are not cytotoxic, non-sensitizing or irritating. That is a necessary step for market approval. Okay.

That's great, actually. Okay, that's it. This is the end of the interview and thank you so much for your valuable time and your information.

(5:17 - 5:21)
Oh, you're welcome. And I wish you all the best. Thank you so much

Appendix 2: Interview Questions

1. Based on your clinical or technical knowledge, what skin reactions have you seen from wearable ECG monitoring continuously?
2. How do you evaluate or monitor for adhesive-related skin reactions in ECG monitoring patients?
3. Based on your technical knowledge, how do different adhesive materials impact both skin compatibility and ECG signal quality?
4. Have patients reported any discomfort or discontinued usage due to skin reactions, and how does this affect your clinical workflow or device performance?
5. Have you seen any design features operational for wearable ECG sensors to make your skin safe, or have you implemented them in a device?
6. How would manufacturers improve the sensor design or material to prevent skin irritation on wearable ECG sensors?
7. In your professional practice, have there been any regulatory concerns or skin reaction safety notifications associated with these devices?

Appendix 2: Ethics Form

Ethics Application &Declaration Form

DISSERTATION TITLE: **"TO INVESTIGATE CHALLENGES ASSOCIATED WITH ADHESIVE SKIN REACTIONS IN WEARABLE ECG SENSORS"**

RESEARCHER'S NAME: SONA THOMAS

PROGRAMME OF STUDY: MASTERS IN MEDICAL DEVICE TECHNOLOGY AND BUSINESS

SUPERVISOR'S NAME: PHILIP BYRNE

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/orethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE:

DATE: 09/07/2025

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☒

SUPERVISOR SIGNATURE: P Byrne

DATE: 10/07/2025

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

Wearable ECG sensors successfully improved cardiac monitoring through allowing real-time and continuous tracking of cardiac activity. However, the prolonged application of this device can cause adhesive-associated skin reactions like rashes, allergic contact dermatitis and irritation. This can be found in users who have sensitive skin or are suffering from chronic conditions. The adverse reaction of these devices compromises the comfort of users, overall efficacy of the device, and adherence to monitoring protocols. The requirement for increased wear time in home and clinical settings can exacerbate the problems. The research aims to explore the issues associated with adhesive skin reactions for wearable ECG sensors in determining potential solutions for developing the experience of users and the performance of sensors. This topic is linked with the module Medical device measurement and analysis.

This study aims to determine the dermatological challenges brought on by the adhesive used in wearable ECG sensors. Thus, the objectives will be as follows:

1. To identify prevalent dermatological issues associated with extended use of adhesive-based ECG wearable devices, including both irritant and allergic skin reactions.

2. To investigate the role of adhesive composition and physical characteristics in triggering or exacerbating adverse skin responses during prolonged contact with the skin.

3. To evaluate how skin-related side effects impact user experience, particularly focusing on comfort, adhesive durability, and the quality and reliability of the ECG signal acquisition.

4. To assess current medical and commercial approaches used to prevent or reduce skin irritation caused by ECG adhesives in wearable technologies.

5. To develop recommendations for improving adhesive materials and wearable design, aiming to increase dermatological safety and user tolerability in long-term ECG monitoring.

1.2 Research methodology:

The research will be completed by following mono method qualitative approach as per the Research Onion model. In order to implement this, a telephonic interview will be conducted in this research. 8 to 10 participants will be selected based on their job role, such as medical technicians and biomedical engineers, with a minimum of 2 years of experience. Open-ended questions will be formed to collect data from the selected participants.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control/influence of others (e.g. in care/prison); Relatives of ill people (e.g., parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

3.1.If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.
3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1.Outline your participant profile and why you have chosen them for this study

Interview participants in this study include individuals' medical technicians and biomedical engineers, with a minimum 2 years work experience and who have better knowledge on wearable ECG sensors. I have aimed to select 8 to 10 participants. Those participants are chosen because they experience the impact of adhesive-based wearable technology every day, which makes them well-suited to really examine the frequency and severity of skin-related reactions.

4.2 How do you plan to gain access to/contact/approach your participant(s).
A purposive sampling strategy will be applied to access participants, meaning the research will target medical technicians and biomedical engineers. Participants will be reached through professional media, namely LinkedIn. In this aspect, it is essential to create a post with a brief description of the study, including disclosure about participant anonymity and voluntary participation. Participants will be legally informed (informed consent) before completing the interview. I believe this approach is appropriate, it is relevant, accessible, and ethical to approach a special interest group for purposes of research.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1**Participant Information Letter (PIL)for participants**

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2**Informed Consent Form (ICF) for participants**

Yes: My research requires signed consent and I have attached an ICF in the appendices of my application.

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Data includes the original audio recordings of the interview will be safely stored in a Google Drive folder and pen drive and backed up regularly during the research phase, which will not be accessible to any person other than the researcher and which is password protected. All of collected interview data will be anonymized to protect participant's rights. No personally identifiable data will be captured. Data will be retained for 2 years following the end of the study, in accordance with ethical and academic conventions. At the end of that time period any digital records will be deleted in a way that cannot be retrieved. Research data storage protection will be compliant with GDPR, and institutional level ethical requirements around data management, which will consider confidentiality, access, and security of information through all stages of the investigation.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

Will the final dissertation contain any information pertaining to any source that would warrant the use of a Non-Disclosure Agreement (NDA) e.g., industry-based research?

No

7.2 **Student consent**

If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OFDISSERTATION VIVA

8.1 **Viva Recording**

The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary, and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION9:DOCUMENTCHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	YES
9.2 Informed Consent Form (ICF) for participant	YES
9.3 Questions for interviewees/ etc *(can be in draft form)*	YES
9.4 Any other documents e.g., Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

DATE: 09/07/2025

Appendix 4: Participant Information Letter

Participant Information Letter

"TO INVESTIGATE CHALLENGES ASSOCIATED WITH ADHESIVE SKIN REACTIONS IN WEARABLE ECG SENSORS"

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

Hello! I am a student from Griffith College and am conducting this research for my MSc degree. I am doing this study to investigate the topic "To Investigate Challenges Associated with Adhesive Skin Reactions in Wearable ECG Sensors". This research is being conducted only for academic purposes and the motive of this data collection is to collect high-quality and specific data to perform valid and reliable research. Wearable ECG sensors' unfavourable reactions jeopardise user comfort, the device's overall effectiveness, and compliance with monitoring procedures. The issues may be made worse by the need for longer wear times in both clinical and residential settings. In order to identify viable solutions for improving user experience and sensor performance, the study intends to investigate the problems related to adhesive skin reactions for wearable ECG sensors. This subject is related to the Medical Device Measurement and Analysis module. Your identity will not be disclosed so that you can provide true information. Your valuable information will determine the reliability of this research, which will help me to qualify for my MSc Degree.

The objective of this research is to gather detailed and high-quality qualitative data for legitimate and trustworthy research, and it is being conducted exclusively for academic purposes. A telephonic interview will be conducted and the questions will be asked regarding skin problems associated with wearable ECG sensors in your experience. Skin reactions, main factors contributing skin reaction by using wearable ECG sensors, adhesive materials used in the sensors, user experience, current medical and commercial approaches, and recommendation for overcoming the challenges will be the main areas of the interview questions.

Your familiarity with dealing with or using wearable ECG sensors has led to your invitation to join. Your observations help pinpoint practical problems and propose enhancements for ECG adhesive technology.

Please note:

- that participation is voluntary
- that refusal to take part will have no negative consequences
- that consent can be withdraw at any time
- If you need to withdraw at any point, please contact me

There are no such possible risks for you by taking part in this interview.

Your participation will be kept completely private with responses will be anonymised by removing any personal identification. Any publications or debates resulting from this study will not include your name or any other identifiable information.

Original audio recordings and signed consent forms will be safely kept in a Google drive folder and pen drive and backed up regularly during the research phase which is password protected accessible by me and my supervisor. Data will be retained for 2 years following the end of the study, in accordance with ethical and academic conventions. At the end of that time period any digital records will be deleted in a way that cannot be retrieved.

The result of this study will be used solely for my MSc dissertation and submitted to Griffith College. The final work will be achieved in the college library and might be published as online e-journals in future.

You can contact me for further information

Researcher: SONA THOMAS
Affiliation: MSc in Medical Device Technology
Email: Sonathomascvptofficial@gmail.com

[THANK YOU]

Appendix 5: Information consent sheet

Consent to take part in research

To Investigate Challenges Associated with Adhesive Skin Reactions in Wearable ECG Sensors

The researcher retains one copy signed by both them and the participant. The participant should also receive a copy of the consent form as a record of what they have signed up to.

- I [*insert participant name*] voluntarily agree to participate in this research study
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study
- I understand that participation involves medical technicians and biomedical engineers. The collection of data regarding the challenges associated with adhesive skin reaction in wearable ECG sensors
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research, my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview, which may reveal my identity or the identity of the people I speak about.
- I agree to my interview being audio-recorded.
- I understand that disguised extracts from my interview may be quoted in dissertation
- I understand that if I inform the researcher that I or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission
- I understand that signed consent forms and original audio recordings will be retained in encrypted form in Google drive and pen drive with the researcher- until the submission of the dissertation

- I understand that a transcript of my interview in which all identifying information has been removed will be retained for two years.
- I understand that under freedom of information legalisation, I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

Name: SONA THOMAS

Degree Programme: MSc in Medical Device Technology and Business

College Details: Griffith College, Dublin

Contact number: +353 894483478

Contact mail: Sonathomascvptofficial@gmail.com

Signature of participant

[Full Name – Printed]

Signature of research participant

---------- ---------- Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study

---------- ---------- Date

Signature of researcher