AHFE
International

How a human-centred design approach can speed up market acceptance of long-term ECG monitoring devices, covering body shape diversity and being gender and age-inclusive

José Laparra-Hernández[1], Mónica Redón[2], Jorge Valero[1], Ignacio Espíritu-García-Molina[1], Carlos Navarro[2], Paola Piqueras[1], José Navarro[1], Carlos Atienza[1], María Jesús Solera[1], Sara Enrique[2], Nicolás Palomares[1]

[1]Instituto de Biomecánica (IBV), Universitat Politècnica de València, Camino de Vera s/n, edif. 9C, 46022, Valencia, Spain

[2]Analog Devices (ADI), Valencia, Spain

ABSTRACT

Cardiovascular diseases constitute a significant portion of preventable fatalities, underscoring the necessity for early detection and diagnosis to enhance quality of life and mitigate healthcare expenses. While conventional monitoring tools are typically confined to hospital environments, limiting continuous monitoring of high-risk individuals, ambulatory monitoring devices improve the yield of detected pathologies. However, few solutions allow comfortable long-term monitoring systems and still fewer combine event monitoring and real-time access to data, limiting the potential to detect critical and sporadic events like atrial fibrillation or tachycardia, potentially resulting in sudden fatalities.

This paper presents the design of an ambulatory ECG monitoring system based on wearable technology, guided by Human Factors, User Experience, and Lean methodologies for expediting market deployment and ensuring acceptance by clinicians, patients, and markets, thereby reducing time and costs. The work described covers the initial phase of the development process, including conceptual designs, dummy prototypes, detailed designs, and prototype validation with participants. In European and US body shape databases, anthropometric research was conducted to comprehend population variability and determine device shapes and dimensions for signal accuracy and comfort optimisation. An iterative design approach was employed to streamline design and development, aligning with regulatory standards required by regulatory bodies such as MDR and FDA to facilitate defining and validating functionalities, risks, ease of use, comfort, privacy, and satisfaction.

Keywords: Human Factors, UX, Lean, long-term ECG monitor, event monitoring, wearables, chronic cardiac pathologies, Atrial fibrillation, gender, ageing, usability, anthropometry, fitting, thermal comfort

INTRODUCTION

Cardiovascular diseases (CVDs) are the leading cause of death worldwide. An estimated 17.9 million people died from CVDs in 2019, representing 32% of all global deaths. Of these deaths, 85% were due to heart attack and stroke (World Health Organization, 2021). However, early detection and diagnosis can promote

the reduction of deaths, the prevention of disability situations, the improvement of the population's quality of life, and the reduction of healthcare costs (Wolowacz et al., 2011).

Several solutions are available on the market for measuring the heart's electrical activity using electrocardiogram (ECG) tests. The standard hospital method typically involves a 12-lead ECG (Figure 1) (Park et al., 2022). Instead, continuous, remote monitoring allows for more rigorous oversight of patients' conditions, even compared to in-hospital observation (Neri et al., 2023), being necessary to enable long-term monitoring and detect critical events in real-time. The irruption of new wearable devices represents a new approach to monitoring ECG signals for health purposes (Neri et al., 2024). Their simplicity, cost-effectiveness, and prolonged monitoring capabilities are considered alternatives to traditional and more expensive medical equipment (Bouzid et al., 2022). This is especially critical for atrial fibrillation (AFib, which affects .5%-2% of the global population and with increasing incidence) or other non-life-threatening arrhythmias.

Figure 1: Example of 12-lead ECG.

In this context, Analog Devices, a company with extensive experience in electronic components across various sectors, including medical devices, is researching the design of an ambulatory ECG monitoring based on wearable technology. This paper outlines the activities undertaken during the initial phase of the research, which work was based on a human factors plan. This approach **integrates human factors, user experience, and lean methodologies while considering the requirements outlined by the CE mark and FDA regulations**.

HUMAN FACTORS PLAN DEPLOYMENT

A Human Factors (HF) Plan is a comprehensive blueprint for designing a medical device to guarantee its usability and safety and optimise the overall user experience. Through a systematic approach, it outlines strategies to address user needs and preferences, ensuring that the device fulfils the expectations of the product. This is achieved by integrating HF, UX, and lean methodologies and techniques. Furthermore, alignment with the MDR process facilitates expedited compliance with CE mark and FDA regulations while ensuring appropriate market deployment.

In this project, a Human Factors Plan was implemented following the **three main phases** defined by Morales et al. (2023):

- **Learn**: Understanding the intended users' needs, preferences, and behaviours.
- **Ideate**: Generating potential solutions for the identified user needs and challenges. This stage encourages creative thinking and collaboration among multidisciplinary teams.
- **Validate** testing and evaluating the proposed solutions to ensure they meet user requirements and goals.

The process was based on an iterative process to allow for early detection of risks (user, technical, market, etc.) and select the key functionalities, minimising costs due to errors along the design process by enhancing patient and professional satisfaction and considering current and future technical boundaries.

This article is focused on the Learn, Ideate and Validate phase, covering conceptual designs, dummy prototypes, detailed design and prototype validation.

LEARN: FROM NEEDS TO REQUIREMENTS AND RISK ANALYSIS

The initial task involved establishing the design requirements for this device, which was composed of a **patch** adhered to the chest skin and an **enclosure housing** the electronics for cardiac activity monitoring.

Firstly, a thorough bibliographic review was undertaken to identify the boundaries and limitations pertinent to usability and user comfort. This encompassed an exploration of critical standards and usability considerations associated with devices of this nature. Secondly, a benchmark analysis was conducted to identify analogous systems in market circulation and research and development stages. This involved scrutinising scientific and technical literature, market data, and product instructions to discern usability challenges and market limitations hindering widespread deployment.

The outcomes of previous tasks, in conjunction with several sessions involving clinicians and patients, and based on previous ADI experience, have enabled the definition of the following essential **requirements:**

- Optimization of **ECG recording areas**, particularly addressing challenges posed by individuals with high body mass index (BMI) and women with large breasts.
- Enhance recording and **detection algorithms** for conditions like atrial fibrillation and other non-life-threatening arrhythmias.
- Exploration of **novel materials and printed electronics** to ensure both signal quality and user comfort during extended usage.
- Development of an intuitive and **user-friendly platform** for streamlined operation.

The proposed device is expected to be used for extended periods; thus, comfortability is critical. Therefore, the device should be **ergonomic, comfortable, and easy to don on/off** by users. Adapting to various pathologies and body shapes, including gender differences, is essential. For instance, one comfort aspect to consider was the **impact of breast size on women's comfort and signal quality**.

Most of the papers covered by the literature consider only men as women's anatomy might cause reproducibility problems. The approach followed in this project looks to optimise the comfort of patients of both genders and different morphotypes.

Because of the long-term monitoring, the wearable device shall be waterproof to allow patients to shower.

To facilitate interaction between the patient and the wearable device, the feedback provided to the patients shall be primarily visual. However, a secondary mechanism is suggested, e.g. to allow interaction with blind or colour-blinded patients.

On the other hand, the patch should be flexible to ensure patient comfort and be attached to the wearable device.

These data have served as inputs for initiating various workshops to conduct **risk analysis** concerning Regulation (EU) 2017/745 (2017). Two categories of hazards or risks have been identified. The first category includes generic known or foreseeable hazards associated with the product, such as biological hazards, environmental hazards, or inadequate user interface. Subsequently, specific product risks have been determined, considering general safety and performance requirements, and identified through a comprehensive understanding of the product. Their significance has been assessed through an analysis conducted following the standard ISO 14971(2020).

IDEATE: FROM CONCEPTUAL DESIGN TO PROTOTYPES: ITERATIVE TESTS

The design process began with defining the anthropometric requirements of the patch in terms of shape and dimensions, as well as assessing their suitability for the target population of interest: **adult males and females in both the USA and Europe**. The goal was to design a patch to fit as many individuals from the target population as possible.

An anthropometric database of more than 11.000 3D body scans, registered using template-fitting methods, was used for the analysis. The human body shape space was parametrised using Principal Component Analyses (PCA). PCA allows for generating realistic human-shaped models representing specific human morphotypes (Figure 2). Differences in body shape determine the patch's fit and the necessity to consider different solutions.
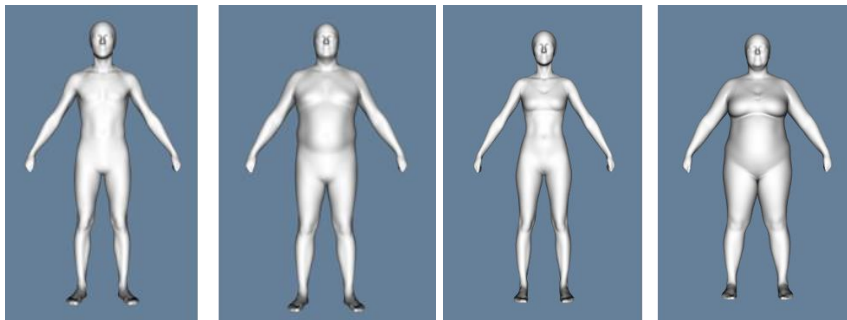
Figure 2: Example of skinny and large morphotypes obtained using PCA.

Then, an optimisation procedure based on Procrustes analysis was conducted over the various possible placements of electrodes on the human chest to determine the **best shape and dimensions of the patch**, considering anthropometric variability.

The next step involved designing the enclosure, focusing on integrating components while ensuring functionality. Exploring three distinct **shape factors** - circular, square, and rectangular - the design team considered aspects like size, weight, and functional mechanics to achieve an efficient system (Figure 3).

Figure 3: Prototypes of the enclosure, presenting various shapes for comparison. Left: circular shape; centre: square shape; right: rectangular shape.

The connection between the enclosure and the patch, concerning the on/off method, was also designed with diverse approaches (Figure 4). The goal was to compare comfort, usability, design considerations, and their **impacts on electronics and functionalities**.

Figure 4: Different approaches considered to put off the enclosure in the patch.

Different tests assessed **durability and breaking points or electronic** degradation due to sweat. The most exciting test was a **thermal test** before starting users' validation. The methodology consisted of the following steps. The patch, resulting from the union of the textile patch and the printed electrode patch, was firstly

adhered to a silicone sample whose properties are very similar to human skin (from now on, it will be called synthetic skin).

The **patch and synthetic skin** ensembles were immersed in water at room temperature for 60 seconds, and after a minimum drying, they were placed on a thermal mannequin. The thermal mannequin used for the test was the ST-2 from Measurement Technology Northwest.

The thermal mannequin was set to 35ºC (average skin temperature). It was placed in a climatic chamber with simulated high temperature and humidity (40ºC and 65% RH) for 3 hours. Figure 5 shows some examples of the testing process.
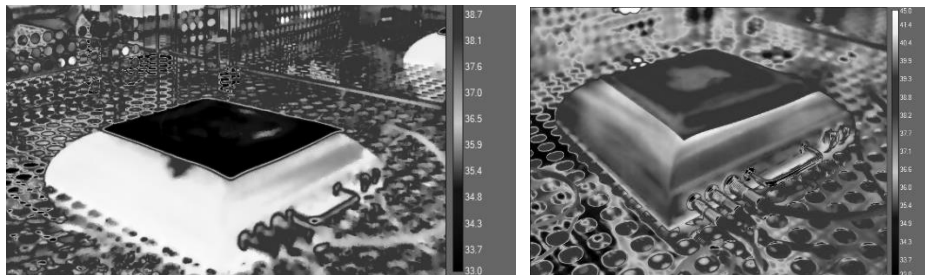

Figure 5: Thermal test based on IBV methodology.

VALIDATE: USER COMFORT TESTS

A comfort assessment was conducted to analyse various preferences regarding the **placement of the device on the chest and the shape of the device**. Specifically, three possible chest locations were considered: beneath the chest, on the breastbone, and above the chest. The three shape factors for the enclosure were examined (circular, square, and rectangular). Furthermore, the test included inquiries about the thermal comfort of the patch. Lastly, the discretion of the device was evaluated, as it can influence patients' acceptance of its use. To conduct tests with potential users, non-functional prototypes were crafted using **rapid prototyping** techniques (Figure 6).

Figure 6: Mock-ups of the enclosures made using rapid prototyping techniques

The comfort test engaged **12 participants**, evenly distributed across genders aged 20 to 60 years. The BMI of the users predominantly fell within the range of 18.5 to 24.9 (67% of users). Users were selected to represent diverse morphotypes and thermotypes within this BMI range.

Each user individually selected the positioning of the device on the chest. All participants tested the three device shapes at this designated location for 15 minutes each. Following this initial period, one of the device shapes was selected for the

user to wear for 5 hours. Participants completed a questionnaire throughout the test to provide feedback on their experience.

Figure 7 shows the comfort levels reported by the participants across all device types in each area of the chest. Remarkably, most of the participants rated the three chest areas as comfortable or very comfortable, with the breastbone area obtaining the best rating. Approximately **88% of users said this zone is comfortable or very comfortable**.
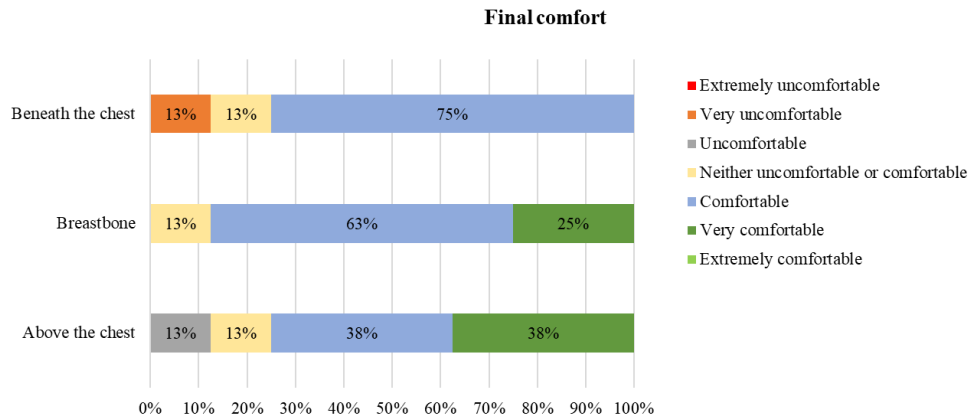
Final comfort

	Extremely uncomfortable
	Very uncomfortable
	Uncomfortable
	Neither uncomfortable or comfortable
	Comfortable
	Very comfortable
	Extremely comfortable

Beneath the chest: 13%, 13%, 75%
Breastbone: 13%, 63%, 25%
Above the chest: 13%, 13%, 38%, 38%

Figure 7: Comfort ratings based on different areas of the patch

Regarding the preference for the location on the chest, the analysis was conducted separately for men and women since **breast shape could influence their comfort assessment**. As depicted in Figure 8, among women, the breastbone area (50% of users) and the area beneath the chest (50% of users) were identified as the most comfortable placement areas. The breastbone area (50% of users) and the area above the chest (50% of users) were reported as the most comfortable for men. When considering users collectively, the breastbone area emerged as the most comfortable placement area for 50%. Notably, the breastbone is one of the flattest and most rigid areas of the chest, facilitating patch adherence.
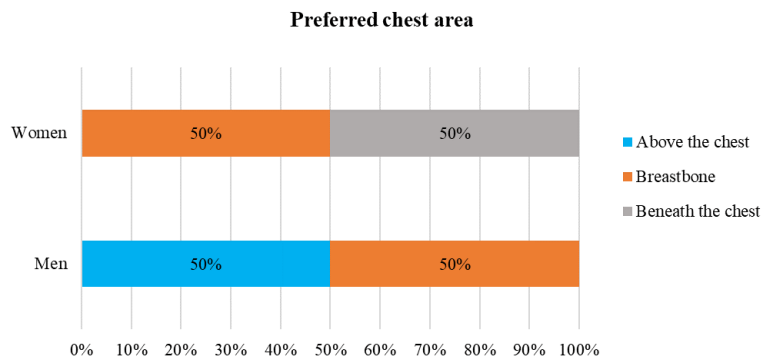
Preferred chest area

	Above the chest
	Breastbone
	Beneath the chest

Women: 50%, 50%
Men: 50%, 50%

Figure 8: Preferred location on the chest for the patch

Concerning the device's shape, **most participants preferred the circular design** as the most comfortable option across all three chest areas.

Participants reported that the patch did not induce increased sweating among users. Wearing the components resulted in a neutral thermal sensation for all users, meaning the elements were neither perceived as warm nor cool.

Furthermore, most participants indicated that the **patch exhibited flexibility and discretion**, regardless of the placement area. However, there was slightly more diversity in opinions regarding the area above the chest. This discrepancy can be attributed to the fact that women wear t-shirts with more necklines compared to men.

CONCLUSIONS

This paper presents the design of a **long-term ambulatory ECG monitoring system** utilising wearable technology, guided by a human factors approach. The integration of this human factors plan, alongside UX and lean methodologies, has facilitated:

- **Reduce time and cost** developments through iterative testing with conceptual designs and dummy prototypes.
- Enable **comparison of various technical solutions with rapid prototyping** before development, ensuring a balance between specifications, technical constraints, and actual user needs.
- **Integrate mechanical and iterative testing** with a limited user sample before embarking on formative and summative evaluations with patients.

This has allowed for the substantial reduction of clinical validations and the avoidance of developments with unneeded functions or **low satisfaction and acceptance of patients and clinicians**.

ACKNOWLEDGMENT

REFERENCES

Bouzid, Z., Al-Zaiti, S.S., Bond, R., Sejdić, E., 2022. Remote and wearable ECG devices with diagnostic abilities in adults: A state-of-the-science scoping review. Heart Rhythm 19, 1192–1201.

Casas, A.M., Vicente, A.L., Solano-García, L., Laparra, J., 2023. 3 sprints from zero to innovative medical device in 16 months: Benefits of combining Human Factors and Agile, in: Production Management and Process Control. Presented at the AHFE (2023) International Conference, AHFE Open Acces. https://doi.org/10.54941/ahfe1003047

EN ISO 14971:2020 Medical devices - Application of risk management to medical devices, 2020.

Neri, L., Gallelli, I., Dall'Olio, M., Lago, J., Borghi, C., Diemberger, I., Corazza, I., 2024. Validation of a New and Straightforward Algorithm to Evaluate Signal Quality during ECG Monitoring with Wearable Devices Used in a Clinical Setting. Bioengineering 11, 222. https://doi.org/10.3390/bioengineering11030222

Neri, L., Oberdier, M.T., van Abeelen, K.C.J., Menghini, L., Tumarkin, E., Tripathi, H., Jaipalli, S., Orro, A., Paolocci, N., Gallelli, I., Dall'Olio, M., Beker, A., Carrick,

R.T., Borghi, C., Halperin, H.R., 2023. Electrocardiogram Monitoring Wearable Devices and Artificial-Intelligence-Enabled Diagnostic Capabilities: A Review. Sensors (Basel) 23, 4805. https://doi.org/10.3390/s23104805

Park, J., An, J., Kim, J., Jung, S., Gil, Y., Jang, Y., Lee, K., Oh, I., 2022. Study on the use of standard 12-lead ECG data for rhythm-type ECG classification problems. Computer Methods and Programs in Biomedicine 214, 106521. https://doi.org/10.1016/j.cmpb.2021.106521

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.), 2017. , OJ L.

Wolowacz, S.E., Samuel, M., Brennan, V.K., Jasso-Mosqueda, J.-G., Van Gelder, I.C., 2011. The cost of illness of atrial fibrillation: a systematic review of the recent literature. Europace 13, 1375–1385.

World Health Organization, 2021. World Health Organization. Cardiovascular diseases (CVDs). Fact sheet, updated June 2021. Available at: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds). Accessed April 3, 2024.