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# PORTABLE, WEARABLE, HOME-BASED. A DESIGN REVIEW OF HOME MEDICAL PRODUCTS FOR HEART FAILURE

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## Abstract

The demographic situation is influenced by several changing dynamics that affect the composition and distribution of the world's population. These dynamics include an ageing population, the increasing prevalence of chronic diseases, and public health challenges. Therefore, home-based management of chronic patients, including those with heart failure (CHF), is preferred whenever possible. This paper presents a design review of home medical products for managing heart failure. The study compares outpatient activities performed within the cardiology department of Ca' Foncello Hospital in Treviso with those performed by patients or caregivers in a home setting. For each activity, such as heart rate measurement or auscultation, the paper identifies the medical devices used. Thus, the paper compares hospital equipment in use for the specific activity with its respective home versions, where available. Each product type will be categorised based on three main characteristics: portability, wearability, and use at home. For each category, case studies of commercially distributed products will be presented, highlighting their strengths and weaknesses. The review will focus on the design aspects of portability, wearability, and suitability for domestic use. The paper will present a preliminary taxonomy and state of the art of homecare products for CHF patients. It will also present their design principles and physical characteristics. Its main objectives are to provide an overview of home-use products for heart failure management and to identify common design principles that can guide designers working in the healthcare field.

**Keywords**: portable devices, wearable devices, home-based device, CHF, medical devices, homecare.

## 1 INTRODUCTION

Public health faces a multitude of challenges, influenced by various factors including demographic shifts, socio-economic disparities and environmental changes. Many countries are facing a significant increase in the proportion of elderly people due to declining birth rates and increased life expectancy (United Nation, 2020). This demographic shift presents challenges related to healthcare and the growing prevalence of chronic diseases that affect public health structures and systems. Therefore, public health policies are increasingly focusing on non-communicable diseases (including chronic diseases), mental health issues and lifestyle-related factors. In this demographic context, home-based management of chronic patients is becoming increasingly significant and necessary. Similarly, self-care is encouraged, with the assistance of family caregivers if necessary (Bjornsdottir & Ceci, 2023).

The combination of an ageing population and a high incidence of chronic diseases is creating new demands for care and assistance, as well as for active ageing, prevention, and ageing in place (Forsyth & Molinsky, 2021). Telemedicine, remote monitoring technologies (including IoT systems) are continuously advancing, allowing healthcare providers to remotely monitor patients' vital signs, symptoms, and medication adherence in real-time. Wearable devices, smart sensors, and mobile health apps are essential in enabling continuous monitoring and timely intervention. Among chronic diseases, heart failure is a challenging chronic condition

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in terms of home management. It is also the most prevalent condition and the primary cause of death and hospitalisation worldwide (Tomasoni et al., 2019; World Health Organization, 2021). Given the ageing population, these conditions are prevalent (WHO, 2022). Moreover, COVID-19 pandemic highlights the importance of the out-of-hospital care of heart failure (Bellicini et al., 2023; Tersalvi et al., 2020).

The scenario described highlights the importance of taking action to reduce the burden on hospitals in favour of home-based chronic care management. To achieve this goal, it is essential to consider the design of products and services to support patients at home.

The paper presents a design review of home medical products for managing heart failure based on fieldwork conducted in a hospital setting. The following sections will present the context and methodology used to obtain the results. Subsequently, medical devices used by CHF patients will be compared, specifically medical equipment and home-use versions. Due to space limitations, the electrocardiograph was chosen as the emblematic device for the analyzed context. Suggestions and information will also be provided for other types of products. The paper concludes by discussing design principles for portable, wearable, and home-based products for managing CHF patients.

## 2 CONTEXT AND METHOD

Traditionally, heart failure care involves two models: “outpatient clinic visits with the use and titration of oral medications, or hospital-based care via the emergency department or inpatient admission, which focuses on decongestion and the use of intravenous diuretics” (Haywood et al., 2023). However, these approaches may not completely align with the changing resource needs and health conditions of individual patients. Telemedicine and home care solutions could be a valid option in the heart disease sector (Anker et al., 2011; Lin et al., 2017; Gensini et al., 2017). However, it is important to distinguish between activities that can be carried out at home and those that require specialized staff in an outpatient setting. And so, identify the necessary devices and tools to accomplish these activities.

The paper presents a collection of observational data that began with a period of field study in a hospital setting (Treviso Hospital). The fieldwork enabled analysis of the activities and workflow within the ambulatory walls, as well as observation of the use of various medical instruments during patient visits. It also facilitated identification of common peculiarities among the examined patients, which are summarised as follows:

- All encountered patients take between 6 and 15 drugs per day.
- Most patients receive assistance from family members, partners, or carers during parameter measurements at home.
- Most patients require assistance, even if only in the form of reminders, when taking their medication.
- All patients visited had other pathologies and/or deficits not directly related to chronic heart disease.
- Many of the patients encountered have a diagnosis of diabetes and/or chronic obstructive pulmonary disease (COPD) at various stages.
- The age range of the patients encountered is between 60 and 85 years.
- Many patients, including those over 75, engage in physical activity.
- Several patients have expressed feelings of abandonment and a desire to increase their self-management abilities. They would like to be able to adapt their therapy according to detected parameters and evaluate its variation based on possible triggering factors.
- Many patients suffer from insomnia or sleep disorders, which can be treated with medication.
- Depression is a common condition among patients.
- Patients often wish to discuss their condition, share their fears and concerns, and ask the doctor many questions during their visit.

The study compares outpatient activities performed within the cardiology department of Ca' Foncello Hospital in Treviso with those performed by patients or caregivers at home. These activities were identified through a close collaboration with cardiologists during the three-month field observation.

The activities are listed as follows and represent the most important factors in evaluating patients with CHF:

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- Heart Rate and ECG measurement
- Weighing
- Boold Pressure measurement
- Therapy monitoring
- Auscultation
- Physical examination
- Leg swelling and Diuresis monitoring.

For each activity the paper identifies the medical devices and tools used in both hospital and home setting. So, the paper compares hospital equipment in use for the specific activity with its respective home versions, where available (Fig.1).

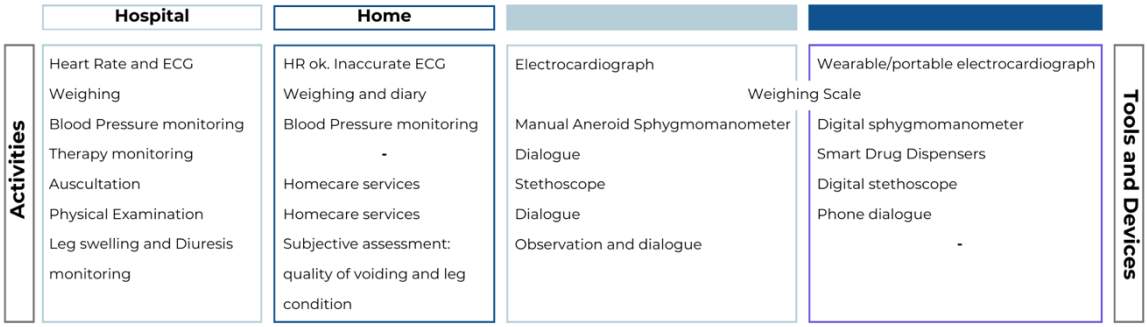


Fig.1: Hospital Care vs. Home Care: A Comparison of Activities, Tools, and Devices

To understand the potential of out-of-hospital activities and to identify the better strategies to support patient at home, the paper proposes a design review of home medical devices for CHF management. Product type will be categorised based on three main characteristics: portability, wearability, and use at home. The next section analyses the aforementioned categories individually and provide examples of current commercial products.

The collection of the state of the art may not be exhaustive, as the evolution of products in this field is constant and there are many variables to be considered in an updated cataloguing. This paper focuses on emblematic cases, those considered to be the most innovative and which have revolutionised the management of pathology in various ways. Victor Margolin emphasises the lack of analysis and the importance of studying the medical equipment design category. He argues that “as a category of design, medical equipment has been little or no examined. I suggest that it provides a rich field of exploration for design historians and design researchers “(2017; p.379)

## 3 MEDICAL DEVICES FOR CHF PATIENTS: A DESIGN REVIEW

The review focuses on the design aspects of portability, wearability, and suitability for domestic use. The scope is presenting a preliminary taxonomy and state of the art of homecare products for CHF patients. Additionally, the paper aims to present an overview of home-use products for managing heart failure and to identify common design principles that can guide healthcare designers.

As mentioned in the previous section, various products are used to manage and monitor patients with heart failure, including electrocardiographs, weighing scale, sphygmomanometers, and digital stethoscopes. The paper distinguishes between wearable, portable, and stationary versions for each type of device as there are several home versions of the products analysed.

### 3.1 Home Electrocardiographs

A 12-channel electrocardiograph with 10 electrodes is currently used for outpatient visits. Its home or out-of-hospital versions are the most common. Several examples for each category will be presented below.

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### *3.1.1 Portable*

Portable electrocardiographs are widely used, ranging from pocket-size products like AliveCor's KardiaMobile 6L (six-lead) or Beurer's ME 90 (one-lead), to handheld products like Gima's Cardio B and Cardio C (three-lead) or FaceLake's FL20 Portable ECG (one-lead), and more complete instruments comparable to hospital ones with a refined aesthetic, such as the D-Heart Bluetooth ECG (8- or 12-lead). The AliveCor (KardiaMobile) solution is widely recognised for its compact and minimalist design. It has won the IF Design Award 2020, making it one of the most popular cardiac monitoring devices. It has even received FDA approval. In comparison to hospital equipment, KardiaMobile performs a six-lead measurement. To record the ECG, the device is held with both hands (first two electrodes) and the lower electrode is placed on the knee or ankle of the left leg (third electrode) (Fig.2). It is one of the first wireless devices that does not require specificscale gel for electrode contact.

Fig.2: KardiaMobile 6L, AliveCor. Source: IF Design Award (*https://ifdesign.com//winner-ranking/project/alivecor-kardiamobile-6l/272089*) AliveCor (*https://www.alivecor.it/kardiamobile6l*)

The D-Heart solution (Fig.3), designed by Design Group Italia and winner of the Compasso d'Oro 2020 award, exemplifies the innovative potential of design in the medical device industry. It is a portable electrocardiograph that can be connected to a smartphone via Bluetooth and customized according to the user's needs. Healthcare personnel can use the twelve-lead function, while personal users can opt for the eight-lead function for self-monitoring. The dedicated app guides the user to correctly position the electrodes using the smartphone's frontal camera, addressing a common issue. Additionally, the cables connected to the electrodes have a simplified and semi-automatic rewinding mechanism, solving another common problem observed in the field experience by health workers. The product's usability has a minor flaw that makes it cumbersome for physicians to use. Specifically, the product is equipped with only four cable electrodes, which forces the operator to move the electrode intended for the precordial leads to the six positions required for the measurement and to restart it each time it is moved during the 12-channel measurement. This can be improved by increasing the number of cable electrodes. The measurement can be sent to the doctor or reported by connecting the product to the associated telecardiology service, which is a positive aspect.

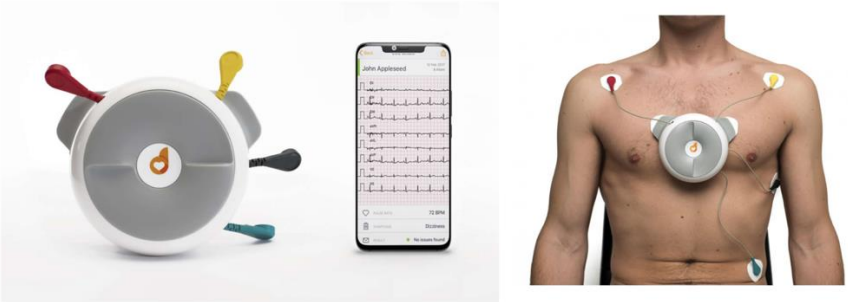

Fig.3: D-Heart ECG device. Source: D-Heart (https://www.d-heartcare.com/en-ex)

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### *3.1.2 Wearable*

Compared to portable electrocardiographs, wearable ones enable continuous monitoring. The use of wearable devices in the medical field is well established, ranging from healthcare to biometric monitoring (Guk et al., 2019), and from pathological treatment to the management of chronic conditions (Lu et al., 2020). In recent years, wearables have evolved into accessories, integrated and smart clothing, skin inserts, and 'skin-attachable devices' (Wu & Luo, 2019). In the context of chronic diseases, this category of products can aid in the remote collection and monitoring of health data in the patient's daily routine, thereby facilitating treatment and lifestyle adjustments (Guk et al., 2019). Cardiology is a medical specialisation in which wearable solutions are popular (Dagher et al., 2020; Ramasamy & Balan, 2018). This is likely due to the nature of the measurements, which are mostly taken in contact with the body.

Due to the vast array of products available, there have been numerous attempts in literature to classify wearable devices based on their product category, measured parameters, body location, monitoring purposes, or areas of use (such as ambulatory, home, or rescue). This paper will focus solely on wearable solutions that offer electrocardiographic examinations at varying levels of reliability. We will filter through the multitude of products available on the market and provide a summary overview of the most significant proposals.

In 2018, the Apple Watch Series 4 revolutionised the health smartwatch category by integrating electrocardiographic trace measurement, demonstrating capabilities like medical instruments in assessing arrhythmia (Ip, 2019). Withings' Move ECG and Scanwatch are also moving in this direction, allowing for ECG measurement by placing the fingertip in contact with the electrode integrated in the watch case. Samsung and Fitbit are among the companies presenting their own versions of medical smartwatches.

The Holter (Fig.4) is a wearable device that allows for dynamic and continuous monitoring of cardiac functions over a 24-hour period. Despite being the first 'out-of-hospital' device used for this purpose, it has not achieved widespread use in home settings due to suboptimal comfort and the conductive gel used with the electrodes, which can cause allergies and skin ulcers on the chest (Lu et al., 2020). The sector of cardiovascular wearable devices is expanding to include patches such as the PeerBridge CorTM and the Zio Patch, as well as chest bands like the QardioCore from Qardio or the CardioVest from Comarch. These devices are becoming viable alternatives to the more traditional cardiac Holter. Barret and colleagues (2014) demonstrated the effectiveness of iRhythm's device, the Zio Patch (Fig.5), by comparing it with the '24-hour Holter monitor', a device commonly used in medical practice, highlighting users' preference for a patch solution that is less invasive and certainly more discreet. As previously stated, the KardiaMobile and Apple Watch have both obtained FDA Class II certification. However, under Italian law, they are not classified as medical devices.

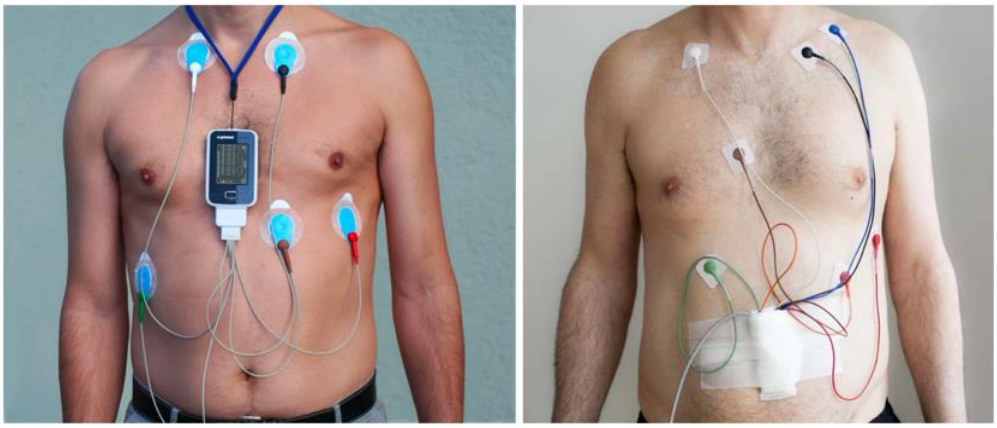

Fig.4: Holter ECG device. Source: MedicalNewsToday (https://www.medicalnewstoday.com/articles/322145)

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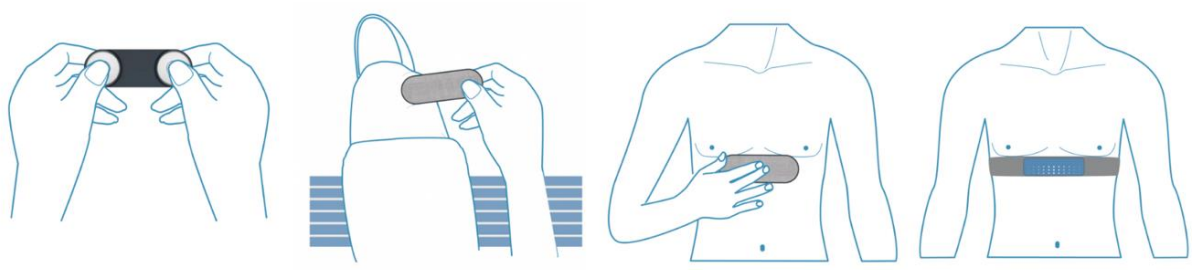
Fig.5: Zio Patch, iRhythm. Source: Zio iRhythm (https://www.irhythmtech.com/)

Our overview of cardiac wearables concludes with a mention of a hybrid solution presented by Wellue. The Wellue DuoEK (Fig.6) is a portable device that can be worn when needed. It is a compact product that allows for point lead I ECG measurement if held with both hands, lead II if held and resting on the leg, and lead thoracic if worn via the supplied band for continuous monitoring lasting fifteen minutes. The collected data is analysed with the support of AI systems.



FiFig.6: DuoEK, Wellue. Source: Wellue (https://it.getwellue.com/)

### *3.1.3 Home-based*

Portable and wearable electrocardiographs are the most used devices.

However, stationary electrocardiographs, which cannot be moved and are used for measurements at a specific location, also exist. In home environments, they are not widely used and are typically reserved for specialized personnel who visit patients in need. The initial remote cardiac monitoring system was achieved using a fixed system called the cardiophone. Invented by SIP in the 1980s, it utilized the telephone line for remote electrocardiogram measurement, representing an early example of telecardiology (L'Unità, 1985).

Wu and Lu (2019) argue that researchers should focus on the implications of user preferences when designing wearable sensor systems. This applies to all devices that enter the patient's daily routine. They also suggest that a body-worn sensor system should be compact, embedded, simple to operate and maintain, and should not affect daily behavior or seek to directly replace a healthcare professional. So, the aim for widespread use of these products is to strike the right balance between reliability, precision, and wearability (Areia et al., 2020).

## 3.2 Other Equipment

As previously stated, CHF patients require various devices to monitor important parameters at home. Unfortunately, it is not feasible to analyse all of them in depth on this paper. Refer to Fig.7 for a summary of other product categories. It should be noted that not all product types have portable, wearable, and home-based versions.

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| | | Portable | Wearable | Home-based |
|---|---|---|---|---|
| Devices | Weighing Scales | | | *Body Cardio*, Withings; *Body Scan*, Withings |
| | Sphygmomanometers | *Ease*, iHealth; *View(BP7S)*, iHealth; *RS7 Intelli IT*, Omron; *Evolv*, Omron; *BPM Connect*, Withings; *Neo*, iHealth; *Qardio Arm*, Qardio | *HeartGuide*, Omron | *HBP-903*, Omron; *RBP-7000/9000*, Raycome; *Moon0*, Moonlife |
| | Digital stethoscopes | *eKuore Pro*, eKuore; *Thinklabs One*, Thinklabs Medical; *CORE Digital*, 3M Littmann; *Eko Core 500*; Ekohealth | *Stethee*, M3DICINE | |

Fig.7: Product Summary: weighing scales, stethoscopes, and sphygmomanometers.

Weighing scales are increasingly powerful and can measure not only weight but also body composition, including lean and fat mass index, as well as BMI (Body Mass Index) and even inferred cardiac control.

Portable sphygmomanometers come in arm and wrist versions, as well as wireless versions with integrated readers in the wearable band. Among wearables, Omron has developed a unique smartwatch-style example. Additionally, there are table-top versions that encourage correct posture during measurement and provide a paper version of the measurement, making them an ideal solution for clinics.

Regarding stethoscopes, the first attempts to digitise the instrument date back to 2010. In 2012, eKuore provided the first commercial version. The main functions include amplifying the sound of the heart and lungs, volume adjustment, and the option to choose between digital or analogue. The collected data can also be stored and shared.

The contemporary trend of integrating the measurement of multiple physiological parameters in a single device has led to innovation and transformation of well-known devices. This goes beyond device kits and includes changes in form, technology, and functionality of individual products. To provide examples, Omron's Complete device integrates a sphygmomanometer with a handheld electrocardiograph, enabling the user to take two primary measurements simultaneously.

Similarly, Withings' BPM Core allows for blood pressure measurement, auscultation, and electrocardiogram deduction, all through a single device. Another example is Eko's Duo ECG, which combines the functions of an electrocardiograph and a digital stethoscope. Fig. 8 presents a visual overview of all devices included in this report.

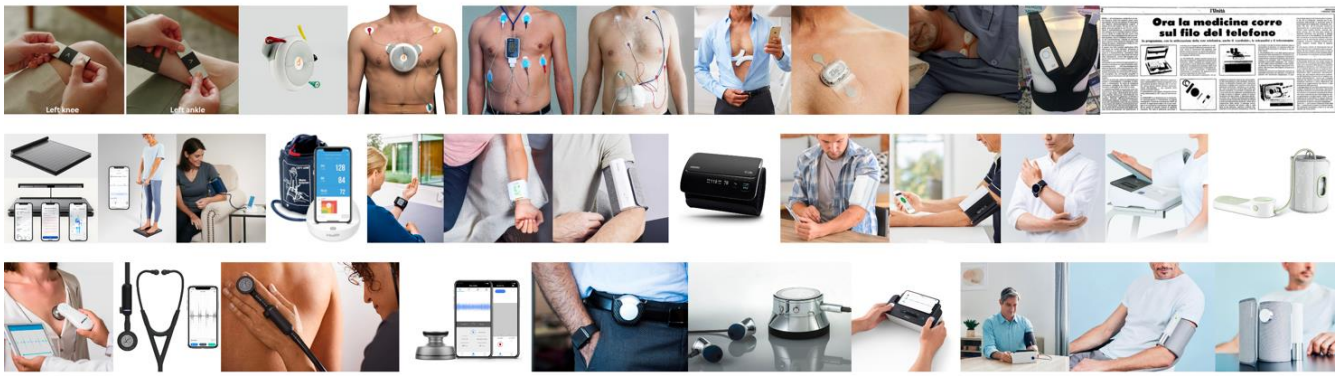


Fig.8: A visual overview of portable, wearable and home-based devices to monitor fundamental physiological parameters in CHF patients.

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## 4 DESIGN CONSIDERATIONS

By analysing the aforementioned categories and examining available devices, recommendations for designing products to manage heart failure patients at home can be identified. Some of these design recommendations may also be applicable to other chronic diseases that could benefit from well-designed devices.

When designing portable medical devices for heart failure, it is recommended to consider the following design features: compactness for easy portability, lightweight for on-the-go monitoring, an intuitive and user-friendly interface for quick and accurate readings, useful data visualization, connectivity options for data sharing with healthcare providers, and a long battery life for extended use.

When designing wearable medical devices, it is important to consider the following recommendations: a comfortable, stylish, and sleek design suitable for continuous and everyday wear; real-time heart rate monitoring with customizable alerts for abnormal readings; integration with a heart failure management app; comprehensive health tracking; long battery life and water resistance for continuous use; integration of sensors into fabric for seamless monitoring; washable and durable material; and continuous monitoring of vital signs without the need for additional devices.

Finally, when designing home-based medical devices for heart failure, it is important to consider the following recommendations. The device features a user-friendly design and is led by a focus on ease of self-use. It also includes a large, backlit display for clear reading in various lighting conditions, memory storage for tracking parameter trends over time, and a compact size with an easy-to-read display. When it comes to electrocardiographs, the device should provide clear instructions for electrode placement to ensure accurate readings and storage capability for multiple ECG sessions. A centralized hub should be used for collecting and transmitting data from various devices, and alerts and notifications should be provided for potential health concerns. Automated dispensing with scheduled medication reminders and clear visual and auditory alerts for dosage instructions should also be included. It should also integrate with healthcare providers for medication adherence monitoring.

In conclusion, when designing products for individuals with chronic illnesses, it is important to consider both technical aspects and the emotional needs of the user. For example, it is important to consider differences in age, technical ability, and physical mobility or dexterity. At the same time, it is necessary to consider the adherence to data security, privacy, and regulatory standards. Robust measures must be taken to ensure the confidentiality and security of health data, and strict compliance with relevant medical device regulations is required for safety and effectiveness.

## 5 CONCLUSION

The main objectives of this paper are to provide an overview of home-use products for heart failure management and to identify common design principles that can guide designers working in the healthcare field. Frausin & Buffagni (2022) provide additional design principles for homecare products, which are divided into fundamental and integrative categories. These principles can also be applied to the management of chronic conditions. The design of portable, wearable, and home-based medical products for heart failure should prioritize user experience, data accuracy, and seamless integration into the daily lives of individuals managing heart failure at home. A co-design approach with regular user feedback and iterative improvements can further enhance the overall effectiveness and usability of these devices.

Despite the wide range of devices that emerged from state-of-the-art research, it is important to note that many of them cannot match the performance of the instruments currently used in outpatient settings. However, this differentiation could be considered necessary and somewhat desirable. Providing complex instruments in the home, even if simplified, that are comparable to hospital services but handled by non-specialised personnel could be risky. For example, imagine having a sophisticated instrument as performing as the one seen in the hands of the specialist at our last check-up, and having to use it on our own at home. Would we still go to the hospital? It is unlikely that we would be able to interpret the data and take necessary action, unlike the doctor who is capable of reading, interpreting and acting. It is widely accepted that what takes place in the hospital, including measurements, is more reliable than what we could do independently at home. “Is require a close consideration and further study, including the effectiveness and safety of these telemonitoring tools in diagnosing, treating and managing heart failure compared to traditional face-to-face doctor–patient interaction” (Gensini et al., 2017). The contribution did not address the technical issues involved in designing medical devices for domestic use specifically. In 2010, the Food and Drug

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Administration (FDA) presented the 'Home Use Device Initiative', followed by the 'Design Considerations for Devices Intended for Home Use' in 2014. These documents provide guidance and clarification for medical device manufacturers on the factors to be considered during the design and development process of a medical device for home use. Both aspects of usability and safety of use should be given special attention, as they are closely linked to the risk factors associated with incorrect use by non-specialised users. The probability of human error increases in home conditions, where individuals may have total or partial autonomy (Pistolesi, 2020).

To summarise the recommendations of the US governmental agency, it is important to consider a range of factors. These include environmental factors such as the location and internal distribution of the home, contaminants, water supply, temperature, humidity, and other external conditions. Additionally, factors related to the user's capabilities, including physical, sensory, perceptual, cognitive, and emotional abilities, should be taken to account. Technical issues that guide the designer's work should also be considered. For instance, a risk management and assessment plan must be drafted (refer to ANSI/AAMI/ISO14971). In 2019, the standard 'Medical devices - Application of risk management to medical devices' was introduced. The purpose of this standard is to provide a system for blocking certain functions of the device, making them inaccessible to the user and controllable only by healthcare professionals. Additionally, the standard aims to minimize the maintenance requirements of the instrument, including cleaning, and to consider the electrical supply of the environment of use, as regulated by the ANSI/AAMI ES60601-1 standard: 2012 - Medical electrical equipment - Part I. When discussing medical devices for domestic use, it is important to consider the portability and mechanical resistance of the instrument. Testing its resistance to shocks and falls is crucial. Additionally, the devices should be designed with minimal detachable or fallible parts. Finally, products should be designed to eliminate the need for user calibration. If this is not possible, a simplified system of steps should be provided, with appropriate feedback communicating the status of the device. Additionally, to simplify the use of the instrument, it is desirable to reduce the instructions for use as much as possible and focus on the product design itself. The product should prioritize human factors, making the role of the designer fundamental and necessary.

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