FAPO-2: Cardiac Patient Monitoring Tool for Clinical Observation and Arrhythmia Detection

Funded by Samsung

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RESUME

Wearable devices, such as smartwatches, have emerged as promising tools in digital health, with expanding clinical applications supported by recent scientific evidence. Studies have demonstrated positive impacts of these devices in cardiovascular medicine, including prevention, remote management of patients with chronic conditions, and arrhythmia screening, as observed in the FAPO-1 study. This project aims to acquire health data through the remote monitoring of cardiac patients using the **Galaxy Watch 6 Smartwatch**, integrated with the Samsung Health and Samsung Health Monitor applications, and the **Huinno™ MEMO Patch** device for short-term electrocardiographic monitoring.

The study will include **520 adult cardiac patients**, stratified by sex (1:1), with a minimum age of 22 years and regular outpatient follow-up. The sample will be divided into four groups: a **Pilot Group (n=15)**, composed of healthy volunteers for usability and functionality validation; the **Extensive Outpatient Monitoring Group (n=150),** monitored using the Galaxy Watch6 Smartwatch™ during the first 30±3 days, followed by 15±3 days using only the Huinno MEMO Patch (total monitoring time of 45±3 days); the **Extensive Post-Intervention Monitoring Group (n=50)**, which includes patients who have recently undergone cardiovascular interventions, following the same monitoring protocol as the Extensive Outpatient Monitoring Group; and the **Optimized Outpatient Monitoring Group (n=305)**, monitored for 15±3 days simultaneously using the Galaxy Watch6 Smartwatch™ (for heart rate and ECG collection) and the Huinno MEMO Patch for continuous ECG recording.

This approach will allow not only for the robust collection of data for analysis, but also the evaluation of adherence, cost-effectiveness, and clinical efficiency across different telemonitoring protocols, contributing to significant advancements in cardiovascular practice.

1. INTRODUCTION

The global landscape of health monitoring is constantly evolving, driven by technological advancements. The accessibility and integration of smart technologies have gained prominence in response to the growing demand for scalable solutions. The widespread use of smartwatches and wearable technologies is evident, especially in monitoring, controlling, and modeling health processes, with a strong focus on the management of cardiovascular patients[1,2].

The increase in life expectancy in developed countries has motivated the advancement of these technologies, transforming perspectives on population aging. Awareness of the importance of preventive measures and healthy habits is growing, resulting from the intersection of progress in both medicine and technology[3,4]. In this context, the fitness & wellness movement plays a fundamental role, promoting a shift in healthcare where individuals become co-responsible for their own well-being and health status[5,6].

The advancement of wearable devices, especially smartwatches, stands out as a promising avenue in digital health. Although still in its early stages, their use as clinical tools is gaining validity, supported by recent scientific evidence[7,8,9]. Rigorous studies have explored the impact of these devices in cardiovascular medicine, covering prevention, arrhythmia screening, and remote management of chronic cardiac patients, including those in the postoperative period, as demonstrated in the previous FAPO-1 study[10,11,12].

The integration of technological functionalities—such as accelerometers, photoplethysmography, and the ability to perform single-lead electrocardiograms (ECG)—allows for the reading of multiple clinical parameters, both quantitative and categorical. These data complement medical assessments, supporting clinical decision-making and enhancing the quality of healthcare delivered[13,14].

In addition, computational statistical methods like *machine learning*—including supervised and semi-supervised approaches—are increasingly being used to capture and analyze health information. Machine learning, coupled with process automation, enables algorithmic learning for artificial intelligence applications in the detection and development of innovative digital health screening methods[15]. The use of these technologies as auxiliary tools promotes a paradigmatic shift in healthcare, offering new perspectives for clinical

monitoring and follow-up regardless of the patient's required technological complexity[16,17].

Cardiovascular care stands out in this scenario. Parameters such as heart rate (HR), blood pressure (BP), arterial oxygen saturation (SpO_2), and ECG, monitored by *smartwatches*, provide a comprehensive and accurate view of cardiac activity[18,12]. This modality overcomes the limitations of traditional clinical monitoring methods, especially due to the flexibility and opportunity afforded by continuous data recording[15].

Although wearable devices and their health applications independently offer valuable data, it is crucial to recognize their limitations in providing clinically detailed and individualized information[19]. To bridge this gap, a digital platform for health data management is essential[20]. This platform complements smartwatch readings by aggregating comprehensive information and facilitating evaluation by qualified healthcare professionals. In detecting cardiac arrhythmias—especially Atrial Fibrillation (AF)—*smartwatches* stand out as impactful screening tools for monitored patients, potentially resulting in clinically relevant benefits[21].

AF is the most prevalent arrhythmia in adults, affecting around 60 million people worldwide[22]. It is associated with serious complications, such as pulmonary embolism, stroke, and heart failure, making pragmatic monitoring essential to mitigate risks. By monitoring the electrocardiographic rhythm, early detection of AF onset or recurrence is possible, enabling appropriate medical interventions, including medication adjustments (anticoagulants and antiarrhythmics) and procedures to control heart rhythm[23,24,25]. Continuous or periodic monitoring supports treatment evaluation, allowing for the tracking of disease progression and adjustment of therapeutic strategies as needed[26].

Cardiac rhythm monitoring can benefit various profiles of patients with cardiovascular disease. Beyond the positive outcomes observed in the previous FAPO-1 project, which focused on monitoring post-surgical cardiovascular patients, it is clear that this approach should be extended to chronic cardiac patients and other cardiovascular profiles.

Studies emphasize the high incidence of AF in patients with acute coronary syndrome, valvular disease, and those with pre-existing electrical conduction disorders[27], due to structural dysfunctions that affect cardiac electrical function[28]. This includes chronic patients and those undergoing minimally

invasive procedures such as percutaneous coronary intervention, transcatheter aortic valve implantation, and invasive electrophysiological procedures.

Thus, patients with chronic heart conditions face ongoing challenges and are susceptible to complications requiring continuous care[29]. Continuous or periodic monitoring of AF in these patients is essential for early arrhythmia detection and appropriate therapeutic interventions, including the use of antiarrhythmic or anticoagulant medications, aiming to prevent serious adverse events[30].

In this context, electrocardiographic rhythm monitoring of chronic patients plays a key role by enabling early identification of AF presence or recurrence, and by acting as an important tool for tracking disease progression and identifying triggering factors[31]. Similarly, in patients undergoing minimally invasive procedures, procedural effects combined with the intrinsic structural arrhythmic substrate in various cardiovascular groups increase vulnerability to AF episodes[32].

To overcome challenges in traditional monitoring, the pursuit of technological innovations is fundamental. Studies highlight the importance of extending the monitoring period after procedures such as ablation for paroxysmal AF[33]. The use of smartwatches, due to their flexibility, allows for the capture of AF recurrences outside the intervals of traditional methods, resulting in improved diagnostic outcomes—even in asymptomatic patients[34].

In addition to measuring multiple health parameters, smartwatches stand out in remote telemonitoring by going beyond cardiac electrical conduction. The incorporation of these innovations into clinical settings has become more common and relevant due to their growing popularity in daily life. These devices hold great potential for continuous monitoring of heart rhythm and health parameters, allowing early detection of AF events or significant changes in vital signs.

To manage and centralize patient monitoring, the FAPO-SI[3] telemonitoring platform was developed as a result of the FAPO-1 study. It integrates with the Samsung Galaxy Watch 6 smartwatch and the Samsung Health Monitor and Samsung Health apps, enabling precise acquisition of health parameters. Its interface contributes to efficient organization and management of information,

giving healthcare professionals a clear view of the data to identify patterns and deviations.

The platform uses system components to store data on Amazon Web Services (AWS) cloud and in the Integrated Institutional Information System (SI^3) at the InCor data center, ensuring secure handling and storage while maintaining the confidentiality and integrity of information.

The essence of the method lies in the strategic application of Samsung Galaxy Watch 6 wearable devices, integrated with the Health Monitor and Health apps from Samsung, installed on Galaxy series smartphones. This convergence enables the collection of crucial biometric data such as blood pressure (BP), oxygen saturation (SpO_2), heart rate (HR), and enhanced detection of atrial fibrillation (AF) events through single-lead electrocardiograms (ECG).

Additionally, the innovative approach includes the **Huinno MEMO™ Patch** device, intended for continuous ECG data collection (Figure 1). The Huinno™ MEMO Patch plays a critical role by establishing a gold standard for comparison with ECG data from the **Samsung Galaxy Watch 6 Smartwatch**. This addition enriches cardiovascular analysis by providing a continuous and detailed source of the heart's electrical information.

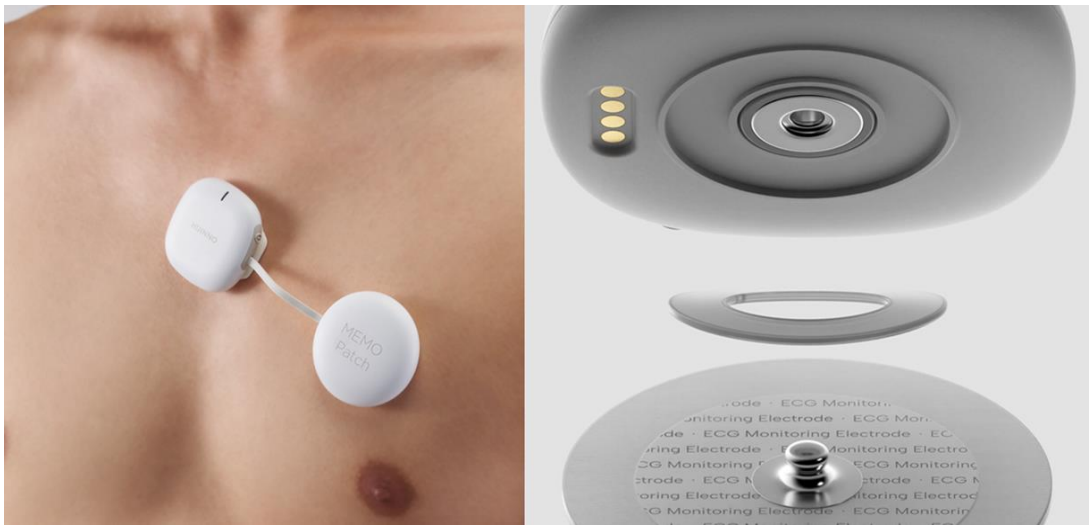

Figura 1. Huinno MEMO™ Patch Device.

The innovation of this project lies in exploring the contribution of these data to care management and clinical decision-making. A key highlight is the advanced development of the artificial intelligence (AI) model, which serves as a

central pillar. The proposal goes beyond optimizing health monitoring—it aims to efficiently prioritize patients based on the data collected by smartwatches.

The complexity of the AI model lies in the detailed analysis of data, exploring correlations between various pathophysiological parameters. This approach seeks to create essential indicators, documented transparently to ensure the quality of the model. The goal is to consolidate an advanced AI strategy that enhances the identification of and response to critical health situations, representing a significant step forward in the use of technology for preventive cardiac care.

The refinement of the remote care model, supported by simple and reliable devices, combined with a data management platform and advanced statistical models, aims not only to optimize efficiency but also to generate economic benefits by reducing unnecessary costs. This innovative approach sets a new standard in the application of technology, allowing for the anticipation of corrective measures, early identification of abnormal situations, and treatment optimization. The development of the AI model is, therefore, crucial to promoting more positive and transformative outcomes for patients undergoing clinical monitoring.

2. OBJECTIVE

2.1. Primary objective

To develop a classification model using data from the ***Samsung™ Galaxy Watch6 Smartwatch*** and the ***Huinno™ MEMO Patch*** device, integrating them into the FAPO-SI³ Web platform to enable accurate patient stratification based on the severity of cardiac conditions, and to allow early detection of complications through continuous monitoring.

2.2. Secondary objective

To enhance the FAPO-SI³ Web telemonitoring platform by introducing advanced features for detailed visualization and analysis of trend curves and the integration of multiple health variables. Additionally, to integrate the ***Huinno™ MEMO Patch*** with the smartwatch for continuous ECG waveform capture, extract

critical information such as heart rhythm fluctuations, and provide accurate management reports..

3. METHODS

3.1 Devices

3.1.1. Samsung Galaxy Watch 6

The *Samsung Galaxy Watch 6* devices are advanced wearables that integrate bioparameter monitoring technology with the functionalities of a smartwatch. Equipped with biosensors such as the *BioActive sensor*—which provides accurate readings of heart rate (HR), blood oxygen saturation (SpO_2), blood pressure (BP), and single-lead electrocardiogram (ECG)—these smartwatches are capable of continuously monitoring the user's heart activity. The Galaxy Watch 6 also offers additional features such as physical activity tracking and sleep analysis. The data collected is synchronized with the *Samsung Health* and *Samsung Health Monitor* apps, allowing users to track their progress and receive personalized guidance to improve their cardiovascular and overall health.

3.1.2. Smartphone

A smartphone based on the Android operating system will be used in synchronized connection via Bluetooth with the *Galaxy Watch 6* and the *Huinno MEMO™ Patch* to store and synchronize the data collected through the app installed on the smartphone, for the collection and transmission of biometric data.

3.1.3. Huinno MEMO™ Patch

The *Huinno MEMO™ Patch* is a cardiac monitoring device that employs integrated biometric sensors to continuously and non-invasively capture electrical cardiac activity. This device is attached using dermal adhesive electrodes, allowing for continuous monitoring of cardiac electrical activity for up to 14

consecutive days. The data collected is stored in the device's internal memory, enabling retrospective analysis. The *HUINNO™ MEMO Patch* is characterized by a discreet and comfortable design, ideal for prolonged use without interfering with the user's daily activities. The *HUINNO™ MEMO Patch* is a product of Huinno Co., Ltd. of South Korea. Approximately 50 units of this device will be imported, as it can be reused with multiple patients after replacing the single-use disposable materials that come into direct contact with the participant's skin.

3.2. Study location

This project will be conducted entirely within the facilities of the Heart Institute (InCor) of the Hospital das Clínicas, Faculty of Medicine, University of São Paulo (FMUSP).

3.3. Sample Composition

The sample will consist of approximately 520 patients with chronic heart diseases under regular follow-up at the Heart Institute's outpatient clinic. Participants will be divided into four groups: Pilot Group, Extensive Outpatient Monitoring Group, Extensive Post-Intervention Monitoring Group, and Optimized Outpatient Monitoring Group. The first group will consist of clinically healthy participants, and the second group of patients after minimally invasive cardiovascular intervention.

- **Group 1 – Pilot (n=15):** Healthy volunteers without any history or prior diagnosis of arrhythmias or heart disease;

- **Group 2 – Extensive Outpatient Monitoring (N=150):** Patients with chronic heart conditions in regular outpatient care. Monitoring will be conducted using the *Galaxy Watch6 Smartwatch™* during the first 30±3 days, followed by 15±3 days with the *Huinno™ MEMO Patch*. The total monitoring period will be 45±3 days.

- **Group 3 – Extensive Post-Intervention Monitoring (N=50):** Patients who have undergone interventional procedures such as angioplasty or valve implantation. Monitoring will be done using the *Galaxy Watch6*

Smartwatch™ during the first 30±3 days, followed by 15±3 days with the *Huinno*™ *MEMO Patch*. Total monitoring: 45±3 days.

- **Group 4 – Optimized Outpatient Monitoring (n=305):** Stable patients with chronic heart conditions. For 14±3 days, patients will be simultaneously monitored with the Galaxy Watch6 Smartwatch™ (for heart rate and ECG data collection) and the Huinno MEMO Patch for continuous ECG recording.

3.4. Inclusion criteria

- Patients with heart disease, of both sexes, over 22 years old;
- Consent to participate by signing the informed consent form (ICF);
- Assentation to comply with study procedures and requirements;
- Patients indicated for outpatient follow-up due to cardiovascular disease or for surgical or catheter-based interventions (e.g., arrhythmia ablation, transcatheter aortic valve implantation, angioplasty, etc.);
- Low or no risk of skin injury based on the Braden Scale or clinical team's judgment;

3.5. Exclusion criteria

- Presence of skin conditions such as vitiligo, lupus, or atopic dermatitis, as well as wrist tattoos that may interfere with the optical sensor of the *smartwatch*;
- Sensitivity or history of allergic reactions to materials used in wearable devices (***Samsung Galaxy Watch6 Smartwatch***™ and ***Huinno MEMO*™ *Patch***) or related items like adhesives and electrodes;
- Inability to use the wearable monitoring devices properly due to physical, cognitive, or technological limitations;

- Presence of peripherally inserted central catheter (PICC) or arteriovenous fistula;
- Presence of implantable cardiac devices like pacemakers, defibrillators, or cardiac resynchronizers that prevent ECG acquisition via smartwatch;
- Diagnosed conditions that cause narrowing or obstruction of the aorta or subclavian arteries (e.g., *Stanford type A* chronic aortic dissection, Takayasu's disease, Subclavian Steal Syndrome, and Kawasaki disease), as these can affect pressure differences between upper limbs and influence assessments in the study;

3.6. Study design

Patients will be selected aiming for a 1:1 gender ratio in the sample composition. Special emphasis will be placed on ethnic diversity, expanding the inclusion of patients with Fitzpatrick skin types V and VI (Annex 8.2). The sample will also be enriched by including individuals with higher body mass index (BMI) and a broad age range, especially those over 40 years old, to reflect the demographic diversity of the target population.

There is a special interest in including participants with paroxysmal (subclinical) atrial fibrillation (AF), as this condition plays a central role in the study's objectives. Efforts will be made to select patients with a higher clinical risk for paroxysmal AF (particularly in the Outpatient Monitoring Group), despite it being subclinical and hard to detect. These representative traits are not strict inclusion criteria but will help enrich data quality and the comprehensiveness of the research database. The target is to include approximately 40 patients per month during the clinical execution phase.

3.6.1. Pilot Phase

➢ Selection of 15 healthy volunteers, without a history or prior diagnosis of arrhythmias or heart disease, all staff members of the Heart Institute (InCor/FMUSP);

➢ The phase will last approximately 14±3 days, during which each volunteer will be remotely monitored using both the ***Huinno MEMO™ Patch*** and the ***Samsung Galaxy Watch6 Smartwatch™*** in conjunction with the Samsung Health and Samsung Health Monitor apps;

➢ The objective of this phase is to evaluate potential adverse skin reactions to both devices and assess the flow and effectiveness of health data capture;

➢ Observations and tests regarding the synchronization between devices and the FAPO-SI[3] platform, together with the Samsung Health and Samsung Health Monitor apps;

➢ Detailed study of the skin hygiene protocol and proper placement of the ***Huinno MEMO™ Patch***;

➢ Durability, adhesion, and allergic reaction testing of the ***Huinno MEMO™ Patch*** on healthy volunteers;

➢ Use of the Braden Scale to assess the risk of pressure injury [35], and identification of medical adhesive–related skin injury (MARSI)[36] caused by the ***Huinno MEMO™ Patch.***

3.6.2. Recruitment and Selection

➢ Patients with chronic heart disease or those recruited after percutaneous cardiac intervention will be identified in the outpatient clinic at the Heart Institute, FMUSP, provided they meet the eligibility criteria and desired profile for study participation.

3.6.3. Inclusion Outpatient Consultation

➢ Patients selected for the **Extensive Outpatient Monitoring Group (Group 2) (n=105)** and the **Optimized Outpatient Monitoring Group (Group 4) (n=305)** will be invited to participate and will provide informed consent and commitment to the study.

➢ Patients in the **Extensive Post-Intervention Monitoring Group (Group 3) (n=50)** will have a pre-hospitalization outpatient consultation.

➢ Detailed information will be provided during the consultation regarding the study protocol, follow-up, teleconsultations, and device usage.

➢ Patients in **Groups 2 and 3** will initially receive instructions on how to use the ***Samsung Galaxy Watch6 Smartwatch™*** for 30±3 days, for the collection of heart rate (HR), blood pressure (BP), oxygen saturation (SpO_2), and the angina feature (for coronary patients with angina). After this period, in the intermediate consultation, they will receive training on the ***Huinno MEMO™ Patch***.

➢ Patients in **Group 4** will receive complete instructions during the initial consultation for using both devices (***Samsung Galaxy Watch6 Smartwatch™*** and ***Huinno MEMO™ Patch***), and will be trained to perform spot checks using the Samsung Health, Samsung Health Monitor apps, and other tools from the study.

➢ Health data will be simultaneously collected by conventional methods and the ***Galaxy Watch6 Smartwatch™*** at the time of device installation.

3.6.4. Monitoring of Hospitalization for Interventional Procedures (Group 3)

➢ The clinical team will follow the journey of patients eligible for the study.

➢ Surgical waiting lists and procedures will be monitored, with the identification of post-intervention complications or events.

➢ During the post-intervention period, unexpected events and recovery times will be recorded.

➢ The institutional SI³ platform will be used to track the patient's clinical course, ensuring an ethical and humanized approach while respecting the recovery period.

3.6.5. Intervention

➢ Patients in Group 3 will undergo interventional procedures in the hemodynamics unit;

➢ After the procedure, they will be transferred to the ICU, inpatient unit, or a specialized recovery area, according to clinical need;

➢ During hospitalization, the clinical team will perform continuous evaluations to ensure patient stability.

3.6.6. Post-Cardiac Intervention Evaluation (Group 3)

➢ Patients who meet the inclusion criteria will be invited again to participate and provide informed consent.

➢ During this phase, professionals will reinforce information about the clinical study, follow-up, teleconsultations, and use of the ***Samsung Smartwatch™ Galaxy Watch6*** devices.

➢ Patients will be trained to adjust the smartwatch, perform ECG, BP, HR, and SpO_2 readings, record symptoms, and complete well-being questionnaires.

➢ Simultaneous acquisition of health data will be performed using conventional methods and the ***Samsung Smartwatch™ Galaxy Watch6*** at the time of device setup.

3.6.7. Remote Monitoring and Assisted Monitoring by Teleconsultations (Groups 2, 3 and 4)

➢ Patients will be remotely monitored for approximately **30±3 days** using the ***Samsung Smartwatch™ Galaxy Watch6***;

➢ The devices will collect health data (HR, BP, SpO_2, ECG) via the Samsung Health and Samsung Health Monitor apps, while the FAPO-X system will be responsible for extracting and analyzing this information.

➢ Patients will perform daily measurements (3x/day), record symptoms, and respond to questionnaires.

➢ Remote follow-up will be carried out through teleconsultations, during which healthcare professionals will review collected data, ECG records (PDF), reported symptoms, and provide personalized guidance as needed.

- **● Group 4 (Optimized Ambulatory Monitoring)**

➢ Patients in this group will be remotely monitored exclusively for heart rate (HR) through the FAPO SI³ platform.

➢ The goal is to assess participant engagement, allowing a partial clinical assessment based on usage patterns.

➢ If HR abnormalities or patient-reported symptoms are detected, teleconsultations will be scheduled for more detailed clinical evaluation.

➢ If the smartwatch ECG shows abnormalities, the patient will be immediately called in for medical evaluation.

3.6.8 In-Person Follow-up Consultation (Groups 2 and 3)

➢ After 30±3 days, patients in Groups 2 and 3 must return to the institution for an in-person outpatient visit.

➢ During this visit, the Huinno MEMO™ Patch will be allocated, along with instructions on:

- Proper device usage
- Daily electrode replacement
- ECG acquisition using the Spotcheck app
- Safe storage of the device until return at the final consultation

➢ Healthcare professionals will assess patient progress, review collected data, perform physical exams, and discuss the individualized care plan.

3.6.9. Survey Closure Query (All Groups)

All participants, regardless of their group, will take part in a final visit at the end of the monitoring period. This visit aims to consolidate clinical and technological data collected during the study, assess the intervention's impact on patient health, and gather detailed feedback on the experience with the devices.

During the visit, the following steps will be conducted:

- **Physiological Data Acquisition**

➢ Simultaneous collection of health parameters using both conventional methods and the SAMSUNG Smartwatch™ Galaxy Watch6, including:

➢ ECG, blood pressure (BP), heart rate (HR), and peripheral oxygen saturation (SpO_2) – when applicable.

➢ In cases where BP and SpO_2 measurement is not feasible, only HR and ECG will be recorded.

- **Data Extraction and Analysis**

➢ Complete transfer of data collected by the devices to the FAPO SI^3 platform.

➢ Review of accumulated records throughout monitoring, enabling comparative analysis with baseline data.

- **Comprehensive Clinical Evaluation**

➢ Detailed medical history and physical examination to assess the patient’s current health status.

➢ Review of monitored parameters, correlating them with the patient's clinical conditions and observed outcomes.

- **Quality of Life and Satisfaction Questionnaires**

Standardized questionnaires will be administered to assess:

➢ The impact of remote monitoring on patients' health perception and quality of life.

➢ Adherence level to the study, main challenges encountered, and device usability.

➢ Overall impressions regarding the technology used in the study.

- **Post-Study Care Planning and Discussion**

➢ Healthcare professionals will assess patient progress over the monitoring period and record an individualized care plan, if needed.

➢ Personalized guidance will be provided based on clinical findings and the patient's reported experience.

➢ At the end of the visit, a structured perception and satisfaction questionnaire regarding device use (Appendix 8.4) will be administered, enabling a comprehensive evaluation of technology acceptance and impact within the study.

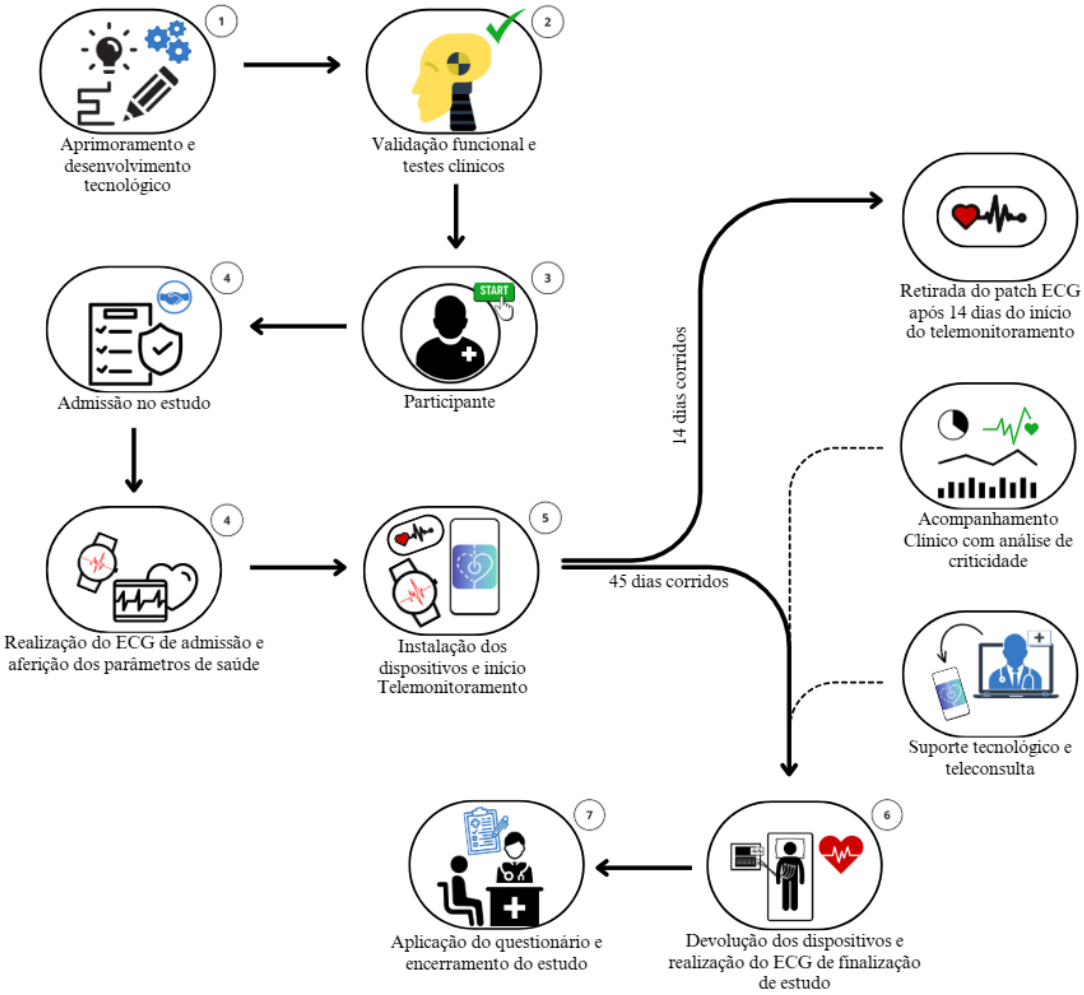

Figure 2. Conceptual diagram of the patient journey flow and data collection for the FAPO-2 study.

3.7. Anamnese completa

After confirming participation in the study, initial clinical assessments will be scheduled. Volunteers will undergo an evaluation of their personal and family health history, with the variables to be collected detailed in the study's Case Report Form (CRF) (Appendix 8.1). In addition, through questionnaires, data will be collected regarding health status, technological perception, and events observed during the remote monitoring phase, covering aspects such as health parameters, symptoms presented, medication use, among others.

3.8. Provision and use of devices

Participants in the ambulatory monitoring group will receive Samsung devices, such as smartphones, the Samsung Galaxy™ Watch6 smartwatch, and the Huinno Memo™ Patch, during the inclusion consultation. For the post-intervention monitoring group, participants will receive the devices one hour prior to the cardiovascular procedure. Participants will sign a loan liability agreement, committing to return the devices and assuming full responsibility for any damage, as detailed in Appendix 8.5.

Data collection will occur over 45±3 days or 15±3 days, with remote follow-up by the team. During the first 14 days, participants will use both the Huinno Memo™ Patch and the Samsung Galaxy™ Watch6 smartwatch; after this period, monitoring will continue exclusively with the smartwatch. Smartphones and smartwatches, using the Samsung Health and Samsung Health Monitor apps, will track HR, BP, SpO_2, and episodes of cardiac arrhythmias (ECG). The Huinno Memo™ Patch will continuously capture ECG for comparative analysis as part of the study outcomes.

All devices will be delivered with pre-installed apps and personalized by the Innovation team. Data will be collected via an embedded application. Participants will return the equipment at the final study visit at InCor.

3.9. Traditional Electrocardiography (ECG) vs SAMSUNG smartwatch ECG

Resting ECG exams will be conducted, and ECGs collected via the Samsung Galaxy™ Watch6 smartwatch to compare standard analysis methods and the device. Gold-standard ECGs will be performed when applying the device, either during the ambulatory visit (ambulatory monitoring group) or one hour before the intervention (post-intervention group), and at the final visit after 45±3 or 15±3 days of monitoring.

All ECGs will be recorded at a speed of 25 mm/sec, calibrated at 1mV/10mm, using the MAC 2000 ECG Machine in an outpatient setting. Electrodes will follow the classic 12-lead configuration. ECGs will be simultaneously recorded by the smartwatch and standard method, allowing for concordance, equivalence, sensitivity, and specificity analyses at the end of the study. Parameters will be assessed by a cardiologist according to the Brazilian Society of Cardiology guidelines.

The smartwatch's intermittent ECG data collection aims to better understand the patient's profile and support machine learning models related to patient severity. Evaluating the concordance, sensitivity, and specificity of data from both standard and smartwatch methods ensures robustness for developing the severity prediction model.

3.10. Measurement of peripheral oxygen saturation by SAMSUNG smartwatch versus standard oximetry

SpO_2 levels will be measured simultaneously using the Samsung Galaxy™ Watch6 smartwatch and the Fingertip-Bewine® digital oximeter during ambulatory consultations (ambulatory monitoring group) and one hour prior to interventions (post-intervention group). During the 45±3 or 15±3 day remote monitoring phase, continuous SpO_2 data will be collected exclusively via the Samsung Galaxy™ Watch6 smartwatch, with participants instructed to take readings three times daily or as prompted by the app. In case of unsuccessful attempts, up to 10 additional attempts will be allowed. If readings cannot be obtained, participants will be asked to wear the smartwatch overnight to measure saturation during sleep.

This continuous data collection aims to understand patient profiles and capture key parameters for machine learning models related to severity, monitoring health status over time. Data from both standard and smartwatch methods will be used to evaluate concordance, sensitivity, and specificity, ensuring robustness for the proposed severity model.

3.11. Blood pressure (BP) measurement by SAMSUNG smartwatch versus standard device

Calibration of the SAMSUNG Galaxy Watch6 smartwatch for BP measurement will be performed during device placement, either at the outpatient consultation (Extensive Ambulatory Monitoring Group) or one hour before the intervention (Extensive Post-Intervention Monitoring Group). After calibration per device instructions, three consecutive resting measurements will be performed, alternating between the smartwatch and a standard arm sphygmomanometer (Welch brand).

During the study's remote monitoring phase (45±3 or 15±3 days), intermittent BP data will be collected exclusively using the Samsung Galaxy™ Watch6 smartwatch. Participants will be instructed to take BP readings three times daily or as indicated by the embedded app. This will allow for detailed comparison between the two methods (systolic and diastolic BP), evaluating concordance, equivalence, sensitivity, and specificity.

The intermittent data collection aims to understand patient profiles and capture essential health parameters for machine learning models related to severity, in addition to monitoring changes in participants' health over time. The evaluation of data from both methods ensures robustness for the development of the proposed severity model.

3.12. FAPO SI³ Platform Enhancement and Health Alerts

Enhancements to the FAPO SI³ platform and health alerts, under the FAPO-2 project, aim to optimize remote monitoring. Initially developed in the previous FAPO-1 project, the platform captured vital health data from the SAMSUNG Galaxy smartwatch, using a specific Android API to extract information from Samsung Health® and Health Monitor® apps. Data were stored in a PostgreSQL database hosted on an AWS EC2 instance and integrated into InCor's Electronic Health Record (EHR), allowing the clinical team to view data from remotely monitored patients, with alerts for specific variables (Figure 3, Table 1).

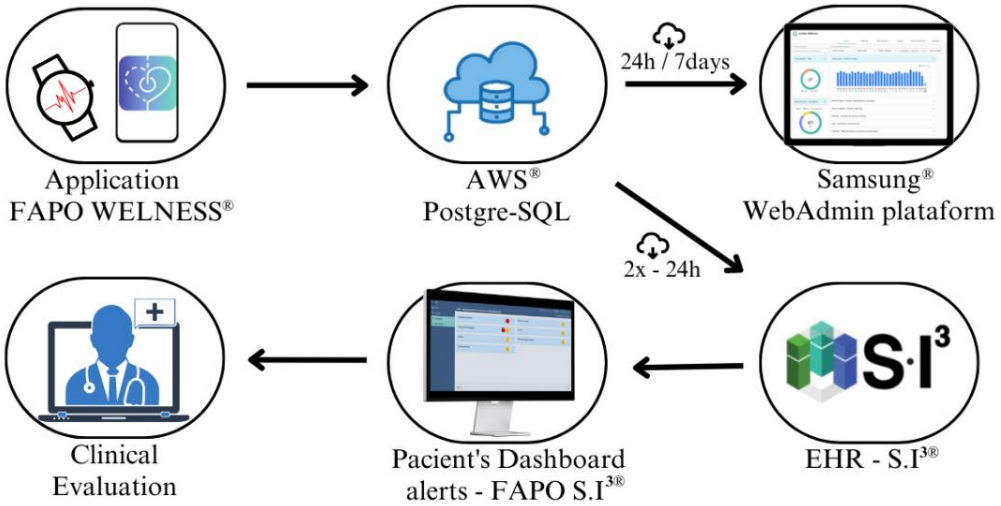

Figure 3. Description of the flowchart for capturing, storing, and managing the study's raw health data. Amazon Web Services (AWS) and EHR SI³ (InCor's Institutional Electronic Health Record).

Table 1. Alert for Parameters Recorded by Smartwatch

Blood Pressure	Normal Range	Systolic [100 – 140 mmHg] and Diastolic [70-90 mmHg]
	Yellow Alert	Systolic [100 – 180 mmHg] and Diastolic [90 – 110 mmHg]
	Red Alert	Systolic [<90 and >180 mmHg] and Diastolic [<60 mmHg and >100 mmHg].
Heart Rate	Normal Range	60–100 bpm.
	Red Alert	HR <50 bpm outside sleep period; HR >100 bpm (evaluated concurrently by the watch)
Oxygen Saturation	Normal Range	95 – 100%
	Yellow Alert	91 – 95%
	Red Alert	<90%

Table 1. Clinical alerts received through the FAPO-SI³ Web telemonitoring platform.

No atual projeto, FAPO-2, estão previstas melhorias significativas, incluindo:

- **Improved Data Extraction:** Optimization of the data extractor (FAPO-X App) to ensure more efficient and comprehensive capture of relevant health information.
- **Development of Dynamic Trend Curves:** Advanced visualization of health parameters to better understand interrelationships between variables.
- **Improvement of the Clinical Records Module:** Efficient synchronization of medical and prescription data with InCor's EHR to optimize real-time clinical decision-making.

- ➢ **Patient Classification Based on Theoretical Criteria:** Group-based classification for personalized healthcare approaches.
- ➢ **Efficient Alerts and Communication:** Health alerts based on pre-established limits will be sent to the multidisciplinary team, promoting early detection of complications.
- ➢ **Detailed Reporting and Efficient Monitoring:** Implementation of reports including metrics such as number of active patients, critical alerts, and resolution time, supporting future scalability evaluation.

These parameters will be incorporated into the platform's system, as illustrated in the hypothetical dashboard in Figure 4.

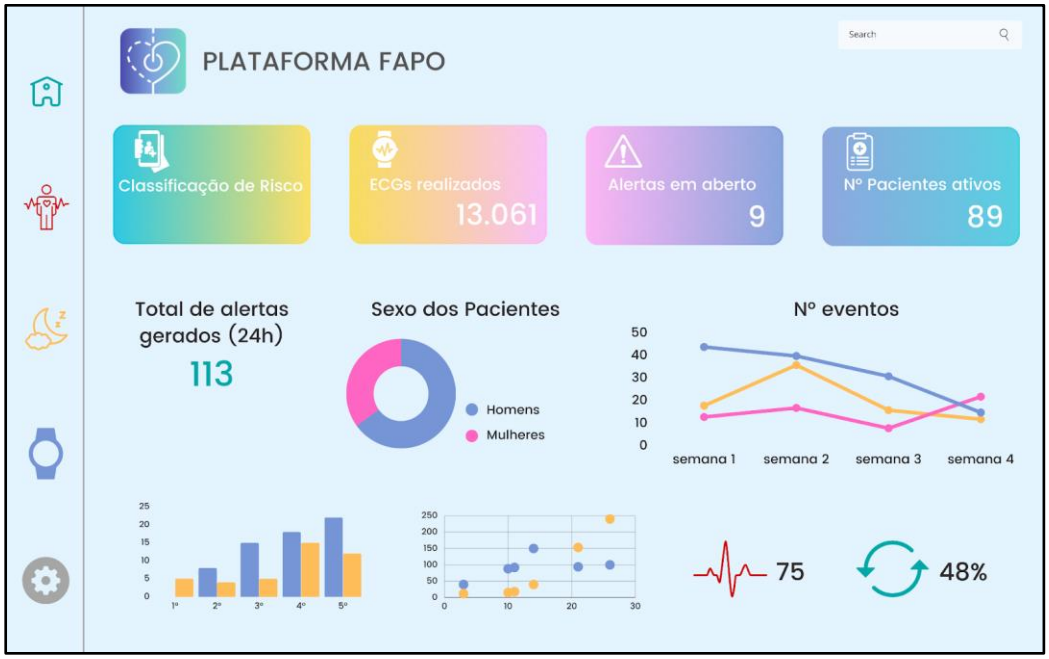

Figure 4. Hypothetical illustrative example of improved control panels proposed as an improvement for the FAPO-SI³ Web platform.

3.13. Advanced Development of Artificial Intelligence Model for Prioritization and Monitoring through Smartwatch

As part of the project, the development of the Artificial Intelligence (AI) model plays a crucial role in prioritizing patients based on data captured by the smartwatch, aiming to optimize health monitoring. The core of the prioritization model focuses on the creation of a classification algorithm capable of alerting to deviations from reference standards and deteriorations in health parameters.

Simultaneously, this clinical study provides essential data for building a robust database. The analysis of the collected data will explore correlations between different pathophysiological parameters, resulting in the creation of indicators for prioritization. This detailed approach will be documented to ensure quality analysis of the model, consolidating an advanced AI strategy that enhances the capacity to identify and respond to critical health situations, significantly contributing to innovation in the care of cardiac patients at varying levels of complexity and severity.

4. ETHICAL ASPECTS

The principal investigator will ensure that the Informed Consent Form (ICF – Annex X) is obtained in accordance with international regulatory specifications and requirements of the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), following the ethical principles established by the National Health Council Resolution (CNS, Resolution No. 466/2012).

This study will be submitted for review by the CAPPesq Research Ethics Committee via the Plataforma Brasil, considering the ethical aspects involved in research with human subjects, as set forth in Resolution No. 466/2012. All data collected from volunteers will be treated with guaranteed confidentiality, in compliance with the requirements of the LGPD (Brazilian General Data Protection Law).

Patient monitoring will be conducted by the multidisciplinary team through the SI³ system, allowing the detection of intercurrences in near real time, with immediate interventions and guidance for patients. After the conclusion of the study, the data will be anonymized and analyzed by the InCor team, and will be made available to the contracting company without any patient identification. Subsequently, the results will be published in scientific journals. During the development and refinement of the AI model, data will be shared by InovaInCor

with the Viva Bem Laboratory in a fully anonymized manner, ensuring the privacy and confidentiality of clinical study participants.

5. DATABASE

The data generated in this study will be processed and anonymized in accordance with CNS Resolution 466/12 and the General Data Protection Law (Law No. 13.709/2018), with the principal investigator designated as the data controller. All data collected for this study will remain under the responsibility of InCor for at least five (5) years after the study's completion.

The database to be established for the operation of this study will undergo rigorous anonymization in accordance with the aforementioned regulations. Initially, all direct identifiers such as full names, dates of birth, addresses, phone numbers, emails, and identification documents such as IDs or institutional registration numbers will be removed from the final database. Full names will be replaced by a randomly generated alphanumeric code, and dates of birth will be generalized to the year only.

The data controller (principal investigator) will use codes to replace identifiable information. These codes will be stored separately from any identifiable data, ensuring the security and privacy of participants. Strict access control protocols will be established to safeguard anonymized data, allowing access only to authorized researchers.

The anonymized database established in this study may be shared by the sponsor with other units of the global Samsung group (affiliates, subsidiaries, parent or controlled companies, including strategic partners both in Brazil and abroad), with the purpose of being used in the future for the development and improvement of algorithms, research, and scientific publications by the Samsung group, not necessarily related to this specific research. This data sharing will be limited to aggregated data analysis without the possibility of individual identification, and does not characterize the partners as co-participating centers in this research project.

6. SCHEDULE

Activity	Month	Bim 1	Bim 2	Bim 3	Bim 4	Bim 5	Bim 6	Bim 7	Bim 8	Bim 9	Bim 10	Bim 11
Project writing and submission to the Research Ethics Committee (CEP) and Plataforma Brasil	1-2	X										
Definition of statistical models	1-2	X										
Software development and maintenance cycles	3-16		X	X	X	X	X	X	X	X		
Study registration and follow-up on Clinical Trials	4-6		X	X								
AI classification model development cycles	3-23		X	X	X	X	X	X	X	X	X	X
Patient selection and recruitment	6-15		X	X	X	X	X	X	X	X		
Inclusion consultation and patient guidance	6-15		X	X	X	X	X	X	X	X		
Data entry in the clinical data collection platform (REDCap)	6-21		X	X	X	X	X	X	X	X	X	
Patient training planning and delivery	5-15	X	X	X	X	X	X	X	X	X		
Hospitalization monitoring for interventional procedures	6-20		X	X	X	X	X	X	X	X	X	
Post-intervention clinical assessment	6-20		X	X	X	X	X	X	X	X	X	
Remote monitoring of patients and collected data for risk identification	6-21		X	X	X	X	X	X	X	X	X	
In-person outpatient visit 45 days after the start of telemonitoring (study inclusion) for evaluation	7-21		X	X	X	X	X	X	X	X	X	
Data analysis	16-19									X		
Preparation of technical-scientific reports and articles for publication	16-19									X		

8. ANEXOS

8.1. Case Report Form (CRF)

CASE REPORT FORM
Ferramenta de Acompanhamento de Pacientes cardíacos para Observação clínica e Detecção de Arritmias **Estudo Samsung FAPO-2**

CLINICAL TRIAL/UNIDADE: INOVA InCor

INVESTIGADOR PRINCIPAL: Dr. Fábio Biscegli Jatene

INVESTIGADOR EXECUTANTE: Dr. _____

I am confident that the information provided in this case registration form is complete and accurate. I confirm that the study was conducted in accordance with the protocol and any amendments to the protocol, and that written informed consent was obtained prior to the study.

Investigator's Signature:

Patient Name

_____

Patient's Name: ----------

Date of Signature:

d	d	m	m		a	a	a	a

Critério de inclusão		**Sim**	**Não**
1	Is the patient over 22 years of age and has a cardiac condition	☐	☐
2	Did the patient voluntarily give written informed consent?	☐	☐
3	Is the patient willing to participate in remote monitoring for approximately 45±3 days or 15±3 days?	☐	☐
4	Does the patient agree to periodically replace the Huinno MEMOTM electrodes over a 14-day period?	☐	☐
5	Does the patient require outpatient follow-up for a cardiovascular disease or have indications for surgical or catheter-based intervention (e.g., ablation for arrhythmias, transcatheter aortic valve implantation, angioplasty)?	☐	☐
6	Does the patient have low or no risk for skin injury based on the Braden scale or clinical judgment?	☐	☐

Critério de exclusão		**Sim***	**Não**
1	Does the patient have skin diseases (e.g., vitiligo, lupus, atopic dermatitis) or wrist tattoos that may interfere with optical sensor readings?	☐	☐
2	Does the patient have a known sensitivity or history of allergic reactions to wearable device components (e.g., Samsung GalaxyTM Watch6 and Huinno MEMOTM patch) or related items like adhesives and electrodes?	☐	☐
3	Does the patient have any physical, cognitive, or technological limitations that prevent proper use of wearable monitoring devices?	☐	☐
4	Does the patient have a PICC (Peripherally Inserted Central Catheter) or arteriovenous fistula?	☐	☐

5 Does the patient have a cardiac implantable device (e.g., pacemaker, defibrillator, resynchronizer) that prevents ECG acquisition via smartwatch? ☐ ☐

6 Does the patient have a diagnosis of conditions that cause narrowing or obstruction of the aorta or subclavian arteries? ☐ ☐

* If any inclusion criterion is marked as **No**, or any exclusion criterion is marked as **Yes**, the patient is not eligible for the study.

VISITE 1 (SCREENING)

Date: _____

DD MM AAAA

DEMOGRAPHIC DATA **Name:** _____ **Hospital Record:** _____									
Age (years):				Sex:	Female		Male		
Follow-up: ( ) 15 days ( ) 45 days									
Height (m):		•							
Weight (Kg):			•						
BMI (BMI = Weight ÷ (Height × Height)):			•						

Ethnicity: _____

Fitzpatrick Skin Type Scale:

I: ( ); II: ( ); III: ( ); IV: ( ); V: ( ); VI: ( );

Sociodemographic Data:

Education Level:

No schooling: ( ); Incomplete primary education: ( ); Complete primary education: ( ); Incomplete secondary education: ( ); Complete secondary education: ( ); Incomplete high school: ( ); Complete high school: ( ); Incomplete higher education: ( ); Complete higher education: ( ); Information not available: ( );

Marital Status: ( ) Single ( ) Domestic Pathernship ( ) Married
( ) Divorced ( ) Widowed

Has a caregiver? ( ) Yes, lives together ( ) Yes, does not live together ( ) No

Household Income: ( ) 2 wages ( ) 2 - 4 wages ( ) 4 - 10 wages ( ) > 10 wages

CLINICAL ASSESSMENT:

Chronic Heart Disease Diagnosis:

( ) Coronary Artery Disease ( ) Heart Failure ( ) Hypertension

( ) Cardiac Arrhythmias ( ) Valvular Heart Disease ( ) Cardiomyopathies

( ) Peripheral Vascular Disease ( ) Cerebrovascular Disease

( ) Deep Vein Thrombosis / Pulmonary Embolism ( ) Endocarditis

( ) Acute Coronary Syndrome

Pre-intervention Disorder:

( ) Persistent AF or AF not responding to medication ( ) Supraventricular Tachycardias

( ) Atrial Tachycardia ( ) Aortic stenosis with high surgical risk

( ) Unstable Angina ( ) AMI ( ) Coronary Artery Stenosis ( ) AF associated with stroke risk

Other, specify

Length of Stay:_____

Paroxysmal Atrial Fibrillation Present: ( ) Yes ( ) No

Type of Intervention Performed:

( ) Cardiac Surgery (CABG, valve, or combined) ( ) Cardiac Ablation ( ) Transcatheter Aortic Valve Implantation ( ) Angioplasty

Other, specify

CONSUMO

Smoker or Former Smoke:

( ) Yes ( ) No

Use History:

( ) Current *(Used for at least 6 months)*

( ) Past *(Used at some point, no use for over 6 months)*

Quantity: _____

Alcohol User or Former Alcohol User:

( ) Yes ( ) No

Use History:

( ) Current *(Used for at least 6 months)*

( ) Past *(No use for over 6 months)*

Quantity: _____

Alcohol use includes reports or records of alcohol consumption, alcoholism, or intoxication. According to the WHO, acceptable weekly consumption is up to 15 units/week for men and 10 units/week for women

Illicit Drug Use:

( ) Yes ( ) No

Histórico de consumo:

( ) Current *(Used for at least 6 months)*

( ) Past *(No use for over 6 months)*

Quantity: _____

CHARLSON COMORBIDITIES:

( ) Previous Myocardial Infarction ( ) Heart Failure

( ) Peripheral Arterial Disease ( ) Cerebrovascular Disease

( ) Dementia ( ) Chronic Lung Disease

( ) Connective Tissue Diseases ( ) Peptic Ulcer Disease

( ) Mild Liver Disease ( ) Diabetes (without complications)

( ) Diabetes (with organ damage) ( ) Hemiplegia

( ) Moderate/Severe Renal Disease

( ) Solid Tumor ( ) Leukemia ( ) Lymphoma / Multiple Myeloma

( ) Moderate/Severe Liver Disease ( ) Metastatic Solid Tumor

( ) AIDS

( ) None

( ) Hypertension ( ) Simple Dyslipidemia ( ) Mixed Dyslipidemia

PHYSICAL ACTIVITY:					
	Yes		No		
If yes, activity intensity: ( ) Light – breathes easily ( ) Moderate – can converse ( ) Vigorous – short of breath but can speak a few phrases ( ) Strong – can speak one word at a time ( ) Intense – breathless, cannot speak Type of Exercise Practiced: ---------- Frequency per Week: _____ Hours per Day: _____					

MEDICATION USE					
Has the subject used any medication continuously or in the past 3 months?					
	Yes		No		
Medication Classes Used? ( ) Antihypertensives ( ) Antiarrhythmics ( ) Antianginals ( ) Anticoagulants ( ) Antidiabetics Outros: _____					

If using antiarrhythmics:
Medication Name: _____ Dosage: _____/____ times per day

STUDY INCLUSION VISIT ASSESSMENT

VITAL SIGNS									
Heart Rate – Standard (sitting)				Bpm					
Heart Rate – Smartwatch (sitting)				Bpm					
Blood Pressure – Standard (sitting)				/				mmHg	
Blood Pressure – Smartwatch (sitting)				/				mmHg	
SpO_2 – Standard (sitting)				%					
SpO_2 – Smartwatch (sitting)				%					

ECG – 12-LEAD

	Normal		Abnormal		**
**Observation*:*	_____				
( ) Sinus Rhythm ( ) Atrial Fibrillation ( ) Atrial Flutter ( ) Atrial Tachycardia ( ) Wide QRS Tachycardias ( ) Bradyarrhythmias ( ) Sinus with Extrasystole ( ) AF with Extrasystole **** Clinical Interpretation: ( ) Sinus ( ) FA ( ) Other**					
ECG - Smartwatch					
	Normal		Abnormal		**
**Observation*:*	_____				
( ) Sinus ( ) Atrial Fibrillation ( ) Atrial Flutter ( ) Atrial Tachycardias ( ) Wide QRS Tachycardias ( ) Bradyarrhythmias ( ) Sinus with Extrasystole ( ) Atrial Fibrillation with Extrasystole **Medical Report: ( ) Sinus ( ) AF ( ) Others ( ) Insufficient Recording** **Smartwatch Report: ( ) Sinus ( ) AF ( ) Inconclusive ( ) Insufficient Recording**					

CLOSING VISIT EVALUATION IN THE STUDY

HEALTH PARAMETERS				
Heart Rate – Standard (seated)				Bpm
Heart Rate – Smartwatch (seated)				Bpm

Blood Pressure – Standard (seated):				/				mmHg	
Blood Pressure – Smartwatch (seated):				/				mmHg	
SpO_2 – Standard (seated):				%					
SpO_2 – Smartwatch (seated):				%					

ECG – 12-Lead					
	Normal		ABnormal		**
**Observations:	_____				
( ) Sinus ( ) Atrial Fibrillation ( ) Atrial Flutter ( ) Atrial Tachycardias ( ) Wide QRS Tachycardias ( ) Bradyarrhythmias ( ) Sinus with Extrasystole ( ) Atrial Fibrillation with Extrasystole ****Clinical Report: ( ) Sinus ( ) AF ( ) Others**					
ECG - Smartwatch					
	Normal		Abnormal		**

**Observations*:*	_____

( ) Sinus ( ) Atrial Fibrillation ( ) Atrial Flutter ( ) Atrial Tachycardias ( ) Wide QRS Tachycardias ( ) Bradyarrhythmias ( ) Sinus with Extrasystole ( ) Atrial Fibrillation with Extrasystole

Medical Report: ( ) Sinus ( ) AF ( ) Others ( ) Insufficient Recording

Smartwatch Report: ( ) Sinus ( ) AF ( ) Inconclusive ( ) Insufficient Recording

LABORATORY ANALYSES **Initial**

Blood for hematology and biochemistry Collected by

✔	**Collection Date (dd mmm aaaa)**											
	Red Blood Cells (milhões/mm³)											
	Hematocrit (%)											
	Hemoglobin (g/dL)											
	MCV (fl)											
	MCH (pg)											
	MCH Concentration (g/dl)											
	Platelets (mm³)											
	CRP (mg/L)											
	BNP											
	Troponin											
	HDL											

	LDL											
	Triglycerides											
	Albumin (g/dL)											
	Glucose (mg/dL)											
	Glycated Hemoglobin (%)											

STUDY CLOSURE FORM

Reason for Study Termination (Please check only the primary reason. Any reason other than Study Completed requires explanation beside the answer.)

☐ Study Completed

☐ Adverse Event/Serious Adverse Event (complete the Adverse Event Form, if applicable):
_____

☐ Lost to Follow-Up: _____

☐ Participant Not Eligible:
_____

☐ Concomitant Medication:
_____

☐ Contraindicated Medication:
_____

☐ Withdrawal of Consent:
_____

☐ Death: _____

☐ Other: _____

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

8.2. Escala Fitzpatrick

1a) What is your eye color?

( ) Light blue, light gray, or light green

( ) Blue, gray, or green

( ) Hazel or light brown

( ) Dark brown

( ) Brownish black

2a) What is your natural hair color?

( ) Red or light blond

( ) Blond

( ) Dark blond or light brown

( ) Dark brown

( ) Black

3a) What is your natural skin color (before sun exposure)?

( ) Ivory white

( ) Fair or pale

( ) Fair to beige with golden undertone

( ) Light brown or olive

( ) Dark brown or black

4a) How many freckles are there on unexposed areas of your skin?

( ) Many

( ) Quite a few

( ) Some

( ) Few

( ) None

Reaction to prolonged sun exposure

1b) How does your skin react to the sun?

( ) Always burns, blisters, and peels

( ) Frequently burns, blisters, and peels

( ) Burns moderately

( ) Rarely burns, if at all

( ) Never burns

2b) Does your skin tan?

( ) Never

( ) Rarely

( ) Sometimes

( ) Often

( ) Always

3b) How deeply do you tan?

( ) Not at all or very little

( ) Lightly

( ) Moderately

( ) Deeply

( ) Naturally dark skin

4b) How sensitive is your face to the sun?

( ) Very sensitive

( ) Sensitive

( ) Normal

( ) Resistant

( ) Very resistant / Never had any issues

8.3. *Mobile Device Proficiency Questionnaire (MDPQ)*

Mobile Device Proficiency Questionnaire (MDPQ-16)

About the MDPQ

This questionnaire asks about your ability to perform a number of tasks with a **mobile device**.

What is a Mobile Device?

A mobile device is a device that allows you to perform many of the same tasks as a standard computer but without the use of a physical keyboard and mouse. Instead, these devices use a touchscreen as their interface between the user and computer programs (called Apps—short for applications).

Mobile devices come in many sizes. Depicted above are two different sized tablets, as well as a smartphone. These are the types of devices we are interested in.

Please answer each question by placing an **X** in the box that is most appropriate.

If you have not tried to perform a task with a mobile device or do not know what a task is, please mark "NEVER TRIED," regardless of whether or not you think you may be able to perform the task. **Remember, you are rating your ability to perform each of these tasks specifically using a mobile device (tablet or smartphone).**

1. Mobile Device Basics

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)
a. Navigate onscreen menus using the touchscreen					
b. Use the onscreen keyboard to type					

2. Communication

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)
a. Send emails					
b. Send pictures by email					

3. Data and File Storage

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)

a.	Transfer information (files such as music, pictures, documents) on my mobile device *to* my computer
b.	Transfer information (files such as music, pictures, documents) on my computer *to* my mobile device

4. Internet

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)
a. Find information about my hobbies and interests on the Internet					
b. Find health information on the Internet					

5. Calendar

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)
a. Enter events and appointments into a calendar					
b. Check the date and time of upcoming and prior appointments					

6. Entertainment

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)
a. Use the device's online "store" to find games and other forms of entertainment (e.g., using Apple App Store or Google Play Store)					
b. Listen to music					

7. Privacy

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)
a. Set up a password to lock/unlock the device					
b. Erase all Internet browsing history and temporary files					

8. Troubleshooting and Software Management

Using a mobile device I can:	Never tried (1)	Not at all (2)	Not very easily (3)	Somewhat easily (4)	Very easily (5)
a. Update games and other applications					
b. Delete games and other applications					

8.4. Fapo-2 User Experience Questionnaire

1. How was your experience using the Galaxy Watch 6 to monitor your health?

● Very unsatisfactory

● Unsatisfactory

● Neither satisfactory nor unsatisfactory

● Satisfactory

● Very satisfactory

2. In one or two words, how would you describe your experience with the watch?

_____, _____

3. How was your experience using the MEMO Patch device to monitor your heart rhythm?

● Very unsatisfactory

● Unsatisfactory

● Neither satisfactory nor unsatisfactory

● Satisfactory

● Very satisfactory

4. In one or two words, how would you describe your experience with the MEMO Patch?

_____, _____

5. Would you continue using or use the smartwatch again after the home monitoring period?

● Yes, definitely

● Yes, probably

● Not sure

● No, probably not

● No, definitely not

6. Would you continue using or use the MEMO Patch again after the home monitoring period?

● Yes, definitely

● Yes, probably

● Not sure

● No, probably not

● No, definitely not

7. Compared to a traditional Holter monitor, how would you rate the MEMO Patch?

● Much worse

● Worse

● Similar

● Better

● Much better

● I have no experience with a traditional Holter monitor

8. How was your overall experience using the phone and the app associated with the devices?

● Very unsatisfactory

● Unsatisfactory

● Neither satisfactory nor unsatisfactory

● Satisfactory

● Very satisfactory

9. How would you rate the ease of using the watch during the home monitoring period?

● Very easy

● Easy

● Neither easy nor difficult

● Difficult

● Very difficult

10. How did you feel wearing the watch in your daily routine? Was it comfortable for long periods?

● Very comfortable

● Comfortable

● Moderately comfortable

● Uncomfortable

● Very uncomfortable

11. How did you feel wearing the MEMO Patch in your daily routine? Was it comfortable for long periods?

● Very comfortable

● Comfortable

● Moderately comfortable

● Uncomfortable

● Very uncomfortable

12. Did you experience any discomfort or issues while using the watch? Please describe briefly:

13. Did you experience any discomfort or issues while using the MEMO Patch? Please describe briefly:

14. Would you recommend the use of the watch to others with similar needs?

● Definitely not

● Probably not

● Neutral

● Probably yes

● Definitely yes

15. Would you recommend the use of the MEMO Patch to others with similar needs?

● Definitely not

● Probably not

● Neutral

● Probably yes

● Definitely yes

8.4. Questionário Intercorrências

1) Over the days you used the watch, how many times do you recall the watch asking you to perform an electrocardiogram (ECG)?

2) Did you need help to perform the ECG on any of these occasions?

( ) Yes

( ) No

3) On any occasion, did you not perform the ECG when the watch prompted you to?

( ) Yes

( ) No

4) Did you find it bothersome to perform the ECG?

( ) Yes

( ) No

5) If yes, why?

_____

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