FAPO-X: Assisted digital telemonitoring with wearables in patients after cardiovascular surgery – a randomized trial

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SUMMARY

1. INTRODUCTION

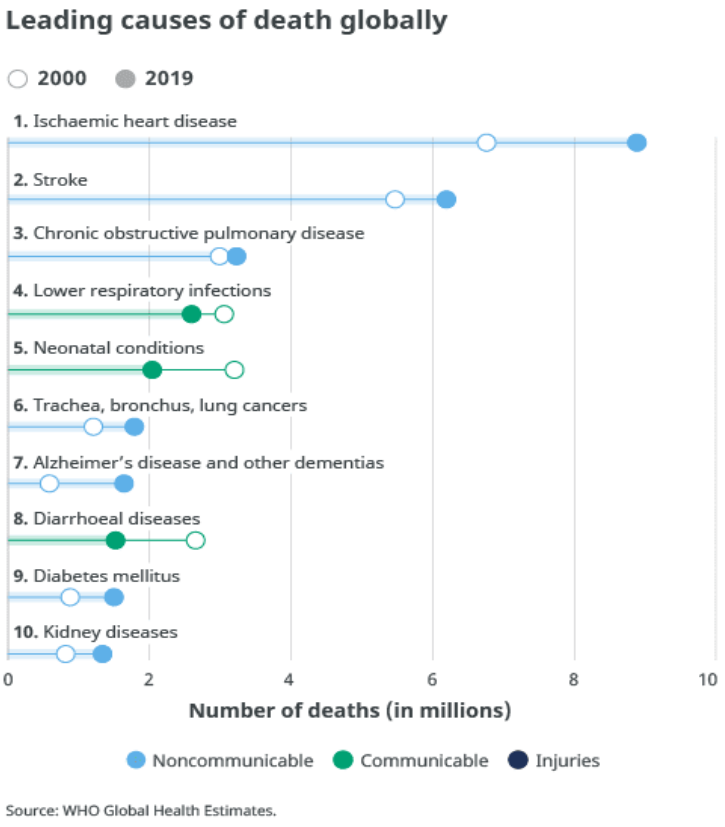
Noncommunicable diseases are responsible for about 41 million deaths/year, which is equivalent to 71% of deaths worldwide [1]. It is no different in Brazil, chronic diseases represent the main challenge in health, about 72% of deaths in the country are due to chronic non-communicable diseases, which represent 75% of the expenses of the Unified Health System (SUS) - Figure 1 .

***Figure 1** . Chronic diseases represent the main health challenge in Brazil.*

The World Health Organization's 2030 Agenda for Sustainable Development reveals the commitment of member countries to a 30% reduction in premature mortality from non-communicable diseases, especially cardiovascular diseases (ischemic heart disease and stroke), cancer, respiratory disease and diabetes [2].

Cardiovascular diseases represent one of the major causes of morbidity and mortality worldwide, which has encouraged numerous researches in different areas. Around 17.5 million people die from cardiovascular diseases annually worldwide, according to data from the World Health Organization (Figure 2). Only in Brazil, diseases related to heart problems correspond to about 300,000 deaths per year. They are chronic and can be treated clinically or surgically [3].

***Figure 2** . Leading causes of death worldwide in the year 2019.*



A significant portion of cardiovascular diseases require surgical treatments, with myocardial revascularization surgeries, correction of valve diseases, followed by surgeries to correct aortic diseases and congenital heart diseases, the most common in adults and the elderly. These patients are usually referred to the operating room with different comorbidities, subject to more complications in the

intra and postoperative period, which leads to an increase in hospital stay and monetary and technological costs invested in their treatment and recovery [4, 5].

Brazil is the second country in the world in number of heart surgeries performed, totaling around 100,000 surgeries/year, second only to the USA, which performs around 300,000 surgeries/year.

There are over 320 million inpatient surgical procedures performed worldwide. Recently, the *International Surgical Outcomes (ISOS) Study (ISOS Group 2016)* highlighted that about 17% of these patients develop one or more complications and, among them, 2.8% die as a result of them [6, 7].

The postoperative period of cardiac surgery requires continuous observation from the health team, quick decision-making and highly complex care. This period presents many challenges for the multidisciplinary team, due to the need for intensive/constant monitoring and the potential postoperative complications. In addition to the lives lost, these postoperative complications dramatically increase hospital and healthcare costs [8].

One of the most frequent complications in the postoperative period of cardiovascular surgery are arrhythmias, with atrial fibrillation being the most frequent arrhythmia in the postoperative period [9]. The prevalence of postoperative atrial fibrillation (POAF) varies between 15 and 40% in coronary artery bypass grafting procedures, 37 to 60% in valve surgery and more than 60% in combined interventions and 24% in patients undergoing heart transplantation.

In 90% of cases, POAF appears in the first four postoperative days [10]. The average length of the first episode is 7-8 hours. Recurrence occurs in 40% of cases and occurs within the first 24 hours. Up to 80% of patients remain in sinus rhythm

24 hours after the first episode. About 14% of patients with atrial fibrillation after cardiac surgery (AFACS) remain with this rhythmic disorder for up to two weeks [11].

Other emerging evidence suggests that POAF is associated with long-term sequelae such as stroke, heart failure, and all-cause [12]mortality.[13]

Despite the advances in the area and the different methods for monitoring POAF, there is still no method that allows the automated evaluation of fibrillation episodes for a very prolonged period. Thus, the detection of POAF becomes an important challenge.

Wearable devices such as *smartphones* and *smartwatches,* are a great promise for screening and monitoring AF, and can present up to 93% sensitivity and 84% specificity when compared to standard ECG [14]. In addition, they are easy to use and allow evaluating the possible adherence of patients to this new modality of assisted telemonitoring. However, to be used as a medical device, these *wearables* need to be accurate in outpatient settings.

Technological resources for health solution

The use of terms such as Internet of Things or *Internet of Things* (IoT), Internet of Everything or *Internet of Everything (* IoE), cloud computing, cyberculture, big data, artificial intelligence, neural networks, wearable devices, among *others* , are already part of our daily lives as innovative technological contributions in the area of health [15, 16].

Wearables are proving to be very effective tools with regard to the prevention, detection or even management of chronic diseases, according to Baig et al [17]. The use of *wearables* to monitor vital signs, such as oxygen saturation (SpO2), heart rate, blood pressure and respiratory rate is of fundamental

importance [18]. In addition, the possibility of generating early warnings in case of clinical instability of the patient was associated with a significant decrease in the number of cardiac arrests and deaths [19]. Statistical data and trend models, even generated from non-medical devices such as *wearables,* are of great value in preventive and predictive actions in health care [20], [21].

The use and implementation of any new technology comes at a cost that must be balanced against the potential savings associated with the expected improvement in postoperative recovery. Postoperative complications are expensive to treat and prolong hospital stays. However, the use of such resources as *wearables* will allow a variety of data to be collected by sensors and allow for earlier interventions [22].

Recent data from a GFK36 global survey on *wearables,* involving more than 20,000 people in 16 countries, found that around 33% use tracking to monitor their health, through apps, bracelets, smart watches and clips. Among those interviewed, 18% had already used the technology some time ago, 45% had never used it and 4% were unable to answer. This survey revealed an interest in wellness, looking for information about exercise, calorie consumption, and even sleep. Another interesting data from this survey is that Brazil occupies, alongside the United States, the second position in the use of health and physical condition monitoring, losing to China and ahead of Germany and France [23].

In this context, the use of available technologies can be used as strategies for faster dehospitalization, with remote monitoring of the patient, since the initial application of *wearables* in surgery may eventually allow better communication and decision-making by the care team through the collection, interpretation and

presentation of patient-specific measurements relevant to the context of the disease [24].

Wearable devices, such as *smartwatches,* can be an innovative and relevant alternative, making it possible to reduce hospitalization periods and the early return of patients to their routine activities safely, in an assisted way.

Integration of wearable technology health data with the electronic record

Currently, Information and Communication Technology (ICT) tools are present in practically all activities related to the health area, such as teaching, research or assistance.

There is evidence that a feasible and adequate electronic health record (EHR) helps professionals in decision-making in patient health care, improving safety and efficiency of care [25]. In view of this, there has been a progressive interest in the medical field in using data captured from the RES, as they contain variables with valuable information, such as demographic data, diagnoses, medications and laboratory data [26, 27].

However, although electronic records serve different purposes and utilize different IT system architectures, there are many operational challenges and technical issues. However, the different needs and subdivisions of the health area, without a systematic view, end up using an exaggerated amount of software and spreadsheets, without interconnection or integration, making it difficult or even preventing the communication and transformation of data into relevant information and knowledge in practice. clinic [28], [29].

InCor's electronic medical record (Integrated Information System InCor - SI^3) provides integrated data from the Clinical Information System via a standard web

interface, which allows independence from the hardware platform *used* for access, in addition to providing better management of health resources in the institution, whether in supplies, occupation of beds, laboratory management, medications, costs of procedures and information that can be obtained in real-time through standardized interfaces [30]. Currently, more than 1.4 million patients are registered in SI3 with all their care data, resulting in more than 500 Terabytes of data. The systems range from scheduling appointments and exams and admitting patients to bed control, laboratory management, medication, supplies and billing to the SUS.

In this way, not only the secure integration of the currently existing databases, but also the coherent use of the stored information, provide a valuable source of knowledge for a better understanding of patients treated by the SUS, thus allowing exploratory, prospective and retrospective studies to produce predictive models, and facilitating decision-making for better management of public health policies.

Wearable technology, such as the use of *smartwatches,* can capture valuable bioparameters, and that at the same time, EHR provides practical platforms for including these data - the creation of a graphical interface that displays patients' health data from these devices could both transform medical care and ensure patient privacy.

In view of the above, the present study aims, through the use of the ***Smartwatch SAMSUNG ™ Galaxy Watch5,*** to validate a measurement model and data analysis that early indicate the need for medical assistance due to atrial fibrillation (AF) in individuals with heart disease undergoing cardiac surgery, as well as to evaluate patients' commitment to a new monitoring routine using regular

alerts based on automated readings, in comparison with the traditional postoperative routine.

The use of such devices as predictors of cardiac alterations could save the SUS hundreds of millions of reais per year, as it would avoid events in these individuals and, consequently, their treatment. To this end, this study will be randomized so that 50 patients will use a ***Smartwatch device SAMSUNG ™ Galaxy Watch5*** *and 50 patients will follow the institution's standard treatment (not monitored by wearables).*

2. OBJECTIVES

2.1 Primary Purpose

telemonitoring platform using the ***Smartwatch SAMSUNG ™ Galaxy Watch5,*** *validating its applicability in patients with POAF.*

2.2 Secondary objectives

- Evaluate the accuracy of the ***Smartwatch SAMSUNG ™ Galaxy Watch5*** in detecting vital signs through optical sensors and, in particular, possible heart rhythm irregularities.
- Compare the results of the variables heart rate, blood pressure and peripheral oxygen saturation (SpO_2) and electrocardiogram provided by the ***Smartwatch SAMSUNG ™ Galaxy Watch5*** with data obtained from gold standard reference equipment.

3. METHODOLOGY

3.1 Place of study

This project will be carried out entirely on the premises of the Instituto do Coração of the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo. The sample will consist of 100 outpatients, with heart disease undergoing cardiac surgery, and selected during the pre -surgical consultation. The sample size was proposed by the contractor because it is a pilot study to evaluate the accuracy of the equipment in a sample with POAF.

3.2 Inclusion criteria

• Be at least 22 years old;

• Parameters for surgical indication, in the presence of heart disease (mitral or aortic valve disease, coronary artery disease or aortic disease);

• Agree to adhere to the study's procedures and requirements;

• Be able to consent to their participation in writing;

• Possess home internet connectivity infrastructure;

3.3 Exclusion criteria

- Not having undergone cardiac surgery;
- Presence of post-surgical complications with prolonged hospital stay for more than 14 days from surgery date;
- Presence of a Peripherally Inserted Central Catheter (PICC) or limb preservation and cardiac pacemaker in case of impediment to acquisition of the ECG (smartwatch);
- Patients with arteriovenous fistula;
- Presence of skin pathology or skin diseases such as vitiligo, lupus and atopic dermatitis, as well as tattoos in the wrist region, which may interfere with the reading by the optical sensor;
- Show sensitivity or allergic reactions, to any degree, to the component materials of the wearable device;

Volunteers who meet the research inclusion criteria will participate in the study protocols after signing the informed consent form (TCLE).

3.4 Selection of volunteers

Patients with heart disease undergoing cardiac surgery, monitored at the InCor outpatient clinic. Randomization will be performed 1:1 using an electronic randomization system and subsequently stratified from the RedCap platform, without knowledge by the team involved in the study. Patients will be randomized to intervention group (teleassisted group) or control group (standard follow-up of the institution)

1. **Control group (N=50):** patients with heart disease who underwent a surgical procedure with standard outpatient and post-surgical follow-up, according to institutional routines and protocols;
2. **Tele-assisted group (N=50):** patients with heart disease undergoing a surgical procedure remotely monitored through *smartwatch* and application.

Adult patients will be included, of both sexes, and ethnic profile representative of the Brazilian population, characteristic of the user population of the Unified Health System (SUS).

re-hospitalization rate, through scheduled consultations and extra intercurrences (clock x institutional standard). As secondary outcomes will be evaluated: technological and treatment adherence, through the use of the mobile application by patients and development and implementation of the telemonitoring platform.

The goal is the inclusion of 40 patients/month (in all, in the 2 study groups: Remotely monitored watch group and group without a watch, following the institutional standard, following the randomization order generated by a specific

system) with 20 in each group of the study. In addition, the inclusion of patients will happen gradually and continuously, with 1 patient per group/working day.

Sem 1	Sem 2	Sem 3	Sem 4	Sem 5	Sem 6	Sem 7	Sem 8	Sem 9
1 ao 5	6 ao 10	11 ao 15	16 ao 20	21 ao 25	26 ao 30	31 ao 35	36 ao 40	41 ao 45
						1 ao 3	4 ao 8	9 ao 13
Sem 10	**Sem 11**	**Sem 12**	**Sem 13**	**Sem 14**	**Sem 15**	**Sem 16**	**Sem 17**	
46 ao 50								
14 ao 18	19 ao 23	24 ao 28	29 ao 33	34 ao 38	39 ao 43	44 ao 48	49 ao 50	
● *Inclusão* ● *Retorno*								

Figure 3. *Flow of inclusion of patients in each arm of the study.*

The remote patient monitoring flowchart to be used in this project is shown in Figure 3. Briefly, it includes:

1. Preoperative outpatient consultation with complete anamnesis to verify eligibility for using the SAMSUNG ***™ Galaxy Watch5 Smartwatch;***
2. Hospitalization, surgery and collection of intraoperative data;
3. Training of the patient and/or family member responsible for the use of *smartwatch* and *smartphone* to start post-operative remote monitoring;
4. Upon hospital discharge, the patient will receive guidance for follow-up on the platform with the ***Smartwatch SAMSUNG ™ Galaxy Watch5*** ;
5. Remote patient monitoring with ***SAMSUNG ™ Galaxy Watch5 Smartwatch*** and app for 30 ± 3 days;
6. Monitoring by InCor's multidisciplinary team of the parameters collected using the ***Smartwatch SAMSUNG ™ Galaxy Watch5*** and an application installed on a *smartphone;* identifying risks for early interventions in the face of any relevant intercurrence;

7. Remote monitoring of the patient by teleconsultation, in case of detection of intercurrences. In cases considered serious by the clinical team, patients will be instructed to seek the InCor PS;
8. Face-to-face return to the outpatient clinic 30 ± 3 days after discharge for evaluation by the clinical team and conclusion of participation in the study.

Figure 4. *Proposed flowchart for the project.*

3.5 Data collection, clinical examinations and evaluation of results

In this project, wearable devices such as the Galaxy Watch will be used. 5 together with Galaxy series smartphones (A or S line) for the acquisition of blood pressure measurements, arterial hemoglobin oxygen saturation (SpO2), heart rate and ECG . This data will be transmitted to a repository, in a secure cloud environment, which meets the requirements of the General Data Protection Act

(LGPD) (Figure 5). In addition, data will be transmitted to a platform to be developed by InCor's IT team, as part of the project, and integrated into InCor's electronic medical record through the WebAdmin tool .

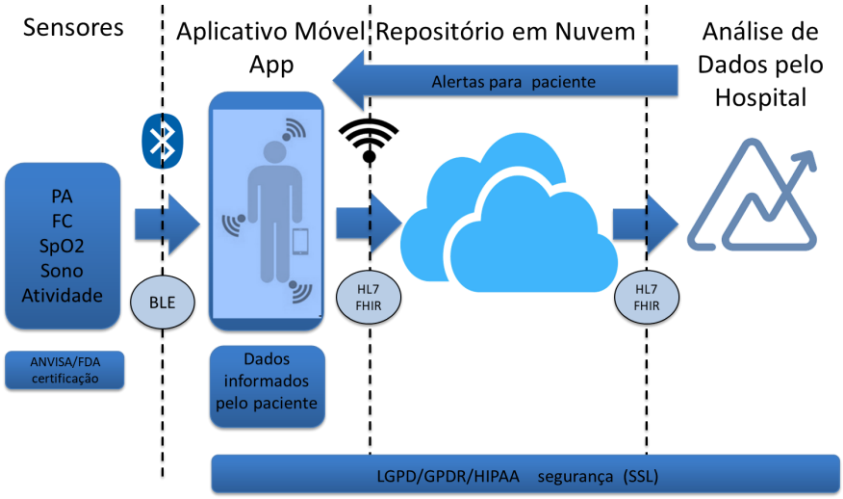


***Figure 5** . Conceptual diagram for the Telemonitoring Platform.*

The division of the study into phases and activities was carried out according to the table and description below.

Phase	Local	Activity
Phase 1	outpatient	• Inclusion of patients • Preoperative consultation; • Meeting with the project coordination team; • Complete anamnesis; • Application of the TCLE; • Collection of additional and contact information;
Level 2	hospitalization	• Hospitalization; • Eventually, some patients may be included in the study after hospitalization, prior to surgery, with the application of informed consent at this time;
phase 3	surgical	• Performing the surgical procedure; • Intraoperative data collection; • Postoperative evaluation and discharge • Patient guidelines; • Signature of the equipment loan liability term (smartphone and smartwatch); and the term for using data from the Electronic Health Record; • Calibration: - BP, serial measurements - *smartwatch* **SAMSUNG** + traditional auscultatory method; - ECG - *smartwatch* **SAMSUNG** + traditional ECG; - SpO2 - **SAMSUNG** *smartwatch oximetry* + traditional oximetry; • Questionnaire of events observed during the remote phase;

Phase 4	remote collection	• Tracking, monitoring and managing each participant's remote data collection for 30 ± 3 days; these being: - Automatically collected: SpO2, heart rate, steps and sleep. - Collected manually: blood pressure and ECG. • Telephone contact, teleconsultations, and unscheduled face-to-face consultations in cases of complications;
Phase 5	outpatient	• Return outpatient consultation; • Meeting with the project coordination team; • Return of equipment used in the remote phase; • ECG - *smartwatch* **SAMSUNG** ; • SpO2 - *smartwatch* **SAMSUNG** + traditional oximetry; • PA - *smartwatch* **SAMSUNG** + traditional auscultatory method; • Quality of life questionnaire adapted to record the patient's perception during the remote monitoring phase; • Issuance of a report confirming or not the classification of the ECG issued by the smartwatch;
phase 6	InCor	• Description of tests carried out and compilation of final results; • Definition, description and justification of the statistical tests chosen and aligned with the hypotheses raised at the beginning of the study.

Table 1: Protocol phases, locations and activities.

3.6. Validation of the Measurement Model and Data Analysis

The measurement validity of *wearables* will be checked against standard reference methods used at InCor, in order to verify the effectiveness of using *wearables* using parametric or non-parametric statistical tests, depending on the normality distribution pattern of the variables to be studied, considering p values <0.05 statistically significant.

The identification, sociodemographic and clinical data of the patients will be registered in the REDCap program, considered as a tool for managing and storing research data[31] and analyzed using *Statistical Package for the Social Sciences* (SPSS) version 22.0 for Windows.

3.7 Complete anamnesis

After confirming participation in the study, initial clinical examinations should be scheduled. Volunteers will be assessed for family and personal health history, and the variables to be collected are described in the case report Form (CRF) of the study (Annex 2).

3.8 Provision and use of SAMSUNG devices (smartphone *and smartwatch)*

SAMSUNG devices will need to be handed over to participants in phase 3 of the study in order for remote data collection to begin. Volunteers must sign a loan liability term that guarantees the return of the device, and coverage in case of damage, as per Annex 3. Longitudinal data collection will be carried out for a period of 30 days ± 3 days, requiring remote monitoring by team. Smartphones and *smartwatches* will be used to monitor adverse events regarding cardiac arrhythmia, heart rate *and* blood pressure. All devices will be delivered with the necessary applications for data collection duly installed. However, customization (login and initial settings) will be carried out by the Innovation team. During phase 4, each participant will remain with **SAMSUNG** devices for 30 days ± 3 consecutive days. Participants must use the *smartwatch* and *smartphone* throughout the day, including while sleeping, and charge the equipment batteries regularly. The data will be collected by an application embedded in the equipment.

During phase 5, the participant must return to InCor for a final consultation of the study, and return of borrowed equipment.

3.8 Traditional electrocardiography (ECG) *versus* SAMSUNG *smartwatch* ECG

Still in phase 3 of the project, resting electrocardiography (ECG) tests will be performed in conjunction with ECG collection from the *smartwatch* **SAMSUNG,** for comparison between the two analysis methods (gold standard vs. device).

All electrocardiograms will be performed at a speed of 25mm/ sec, with 1mV/10mm calibration, in a MAC 2000 ECG Machine (GE Medical Systems Information Technologies, Inc., WI, USA) on an outpatient basis. The electrodes will be placed in the classic way of 12 leads (6 in the frontal plane D 1,D 2,D3,aVr,aVl,aVf and 6 in the horizontal plane V1,V2,V3.V4,V5,V6). The parameters will be evaluated by the clinical cardiologist, who will issue a report, based on the guidelines of the Brazilian Society of Cardiology on analysis and issuance of electrocardiographic reports.

3.9 Peripheral oxygen saturation (SpO_2) measurement by SAMSUNG *martwatch versus* standard oximetry

SpO_2 values will be measured simultaneously by the *smartwatch* **SAMSUNG** and a digital pulse oximetry equipment (G-TECH 302L). Traditional oximetry, using an infrared light beam, simultaneously measures heart rate and peripheral oxygenation in percentages of 0-100%, and measurements above 95% will be considered normal. This evaluation will be carried out in phases 3 and 5 of the project.

3.10 Blood pressure (BP) measurement by SAMSUNG *smartwatch versus* standard device

smartwatch will first be calibrated **SAMSUNG** for BP measurement following the instructions of the equipment itself. From then on, 8 consecutive measurements will be taken, at rest, alternating between using the *smartwatch* **SAMSUNG** and the arm pressure gauge (Brand *Welch)* standard, which uses aneroid meter and pulse auscultation (stethoscope *littman clinic).* Measurements with the standard device will be performed with the patient in the supine position, after 10 minutes of rest with 3 consecutive measurements. Additionally, a measurement will be performed in a sitting position and another measurement in an orthostatic position with a 30-second difference between measurements.

This assessment will be repeated in phase 5 of the project, following the same methodology described above.

3. 11 Definition of alerts – teleassisted group

The multidisciplinary team will receive alerts through the application platform, according to pre-established limits of blood pressure, heart rate and blood oxygen saturation.

- Blood pressure

Normal Parameters: 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 parameters: HR detection between 60-100 bpm.

Red Alert: Detection of HR < 50 bpm outside sleep period; or HR > 100 bpm (concurrently assessed by watch)

- Oxygen Saturation:

Normal parameters: 95 – 100%

Yellow Alert: 91 – 95%

Red Alert: <90%

The conduct and actions planned to be taken by the clinical team after receiving the alerts through the Si3 platform (on D+1), as well as the guidelines that teleassisted patients will receive at the time of hospital discharge, are described in the table below:

INFORMAÇÕES AO PACIENTE

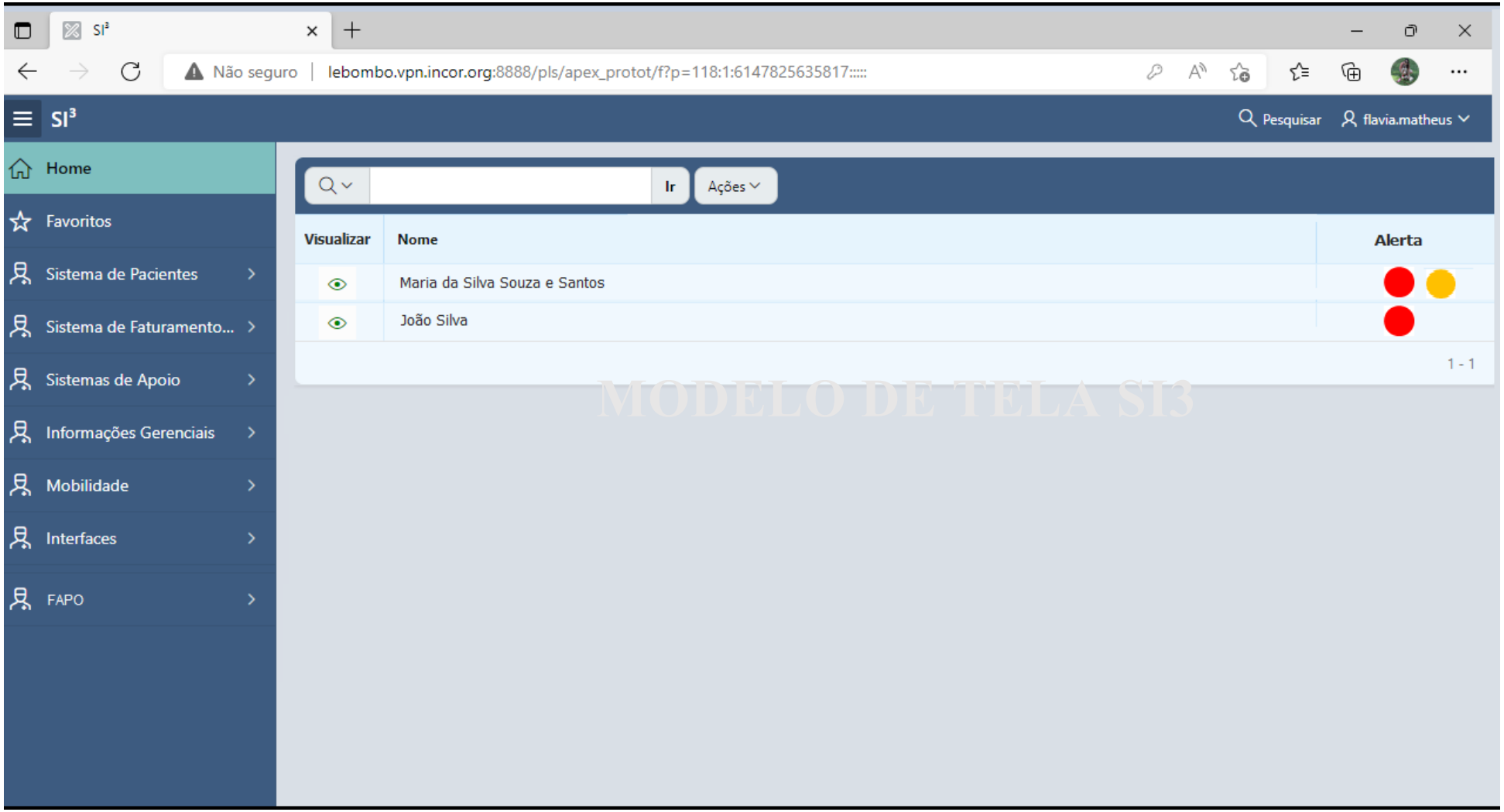
INFORMAÇÕES À EQUIPE CLÍNICA

SITUAÇÃO	ORIENTAÇÃO	INTERVENÇÃO	AÇÃO
Detecção de FC < 50 bpm fora do período de sono	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	Entrar em contato com a enfermeira da equipe pelo telefone	Analisar os parâmetros clínicos e os sintomas do paciente. Enfermeira aciona teleconsulta com o médico se necessário. Em caso de necessidade, o médico orienta o paciente a procurar o PS do InCor
Deteção de FC > 100	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	Entrar em contato com a enfermeira informando o ocorrido	Orienta o paciente a procurar o PS do InCor
PAS: Sistólica < 90 e > 180 mmHg	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	-	Orienta o paciente a procurar o PS do InCor
PAS: Diastólica < 60 e > 110 mmHg	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	-	Orienta o paciente a procurar o PS do InCor
PAS: Sistólica 140 - 180 mmHg	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	Entrar em contato com a enfermeira da equipe pelo telefone	Analisar os parâmetros clínicos e os sintomas do paciente. Enfermeira aciona teleconsulta com o médico se necessário. Em caso de necessidade, o médico orienta o paciente a procurar o PS do InCor
PAS: Diastólica 90 - 110 mmHg	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	Entrar em contato com a enfermeira da equipe pelo telefone	Analisar os parâmetros clínicos e os sintomas do paciente. Enfermeira aciona teleconsulta com o médico se necessário. Em caso de necessidade, o médico orienta o paciente a procurar o PS do InCor
SPO²: 91 - 95%	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	Entrar em contato com a enfermeira da equipe pelo telefone	Analisar os parâmetros clínicos e os sintomas do paciente. Enfermeira aciona teleconsulta com o médico se necessário. Em caso de necessidade, o médico orienta o paciente a procurar o PS do InCor
SPO²: <90%	Realizar medidas de parâmetros indiretos (ECG, P.A. E SPO²)	Entrar em contato com a enfermeira da equipe pelo telefone	Orienta o paciente a procurar o PS do InCor
Sono: < 7 horas contínuas	N/A	Entrar em contato com a enfermeira da equipe pelo telefone	Analisa a possível causa e fornece orientação de Higiene do Sono
Passos: <500 passos	N/A	Entrar em contato com a enfermeira da equipe pelo telefone	Analisa a possível causa e orienta o paciente a aumentar o nº de passos

Table 2. *Flow of care for patients in the study (alerts, guidelines, interventions and actions)*

The institutional electronic medical record (Si3) software modeling that will be used in the project to access clinical and functional information regarding patient data, are exemplified in the figures below:

Figure 6. *Institutional Electronic Health Record: Macro view of the alerts referring to the teleassisted group .*


SI³
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Sistemas de Apoio
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Mobilidade
Interfaces
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Ir
Ações
Visualizar
Nome
Alerta
Maria da Silva Souza e Santos
João Silva
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MODELO DE TELA SI3

Figure 7. *Institutional Electronic Medical Record : Macro view of the alerts referring to each patient that makes up the teleassisted group .*

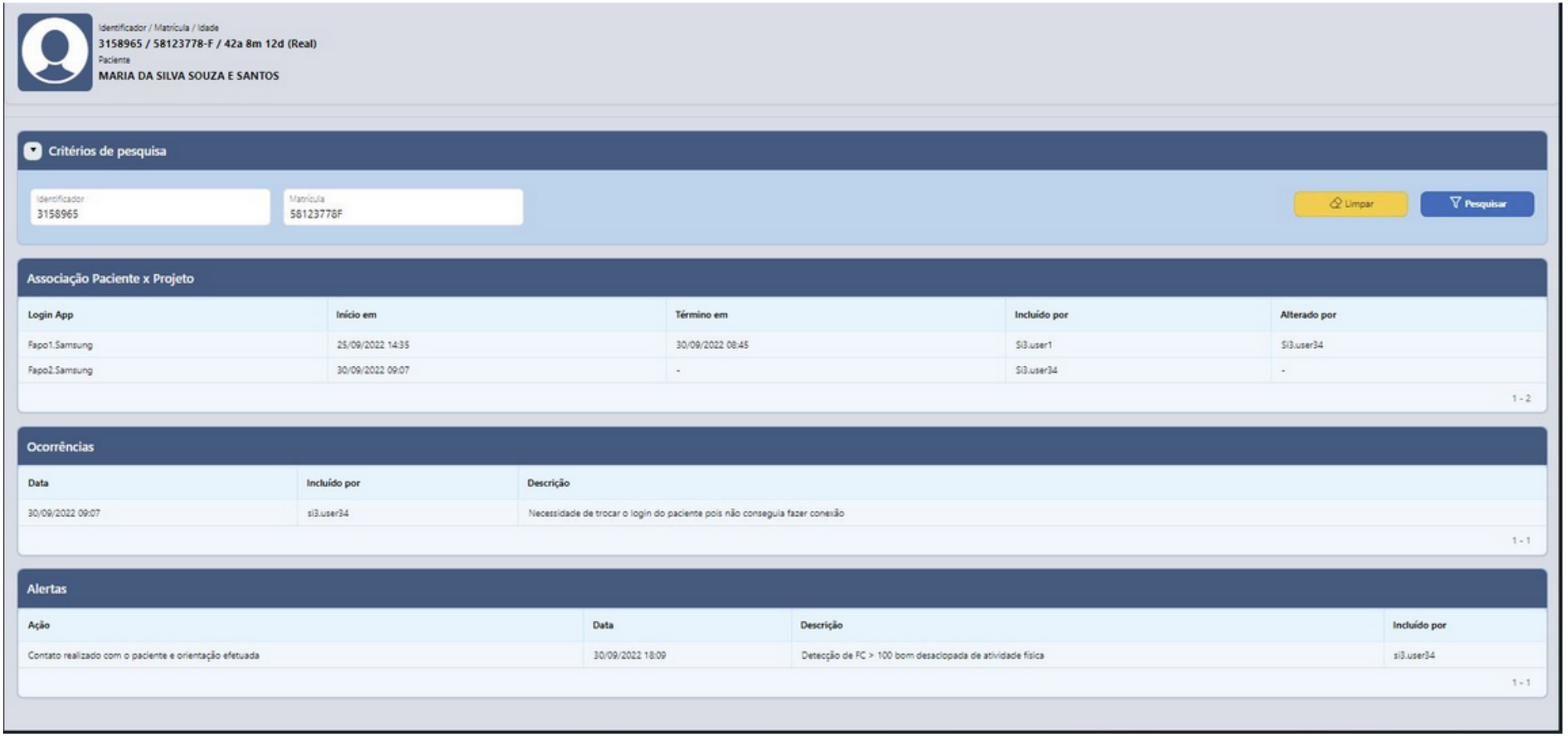

Figure 8. *Institutional Electronic Medical Record : Visualization of alerts referring to the variable and to each patient that makes up the teleassisted group .*

3.1 2 Ethical Aspects

The researcher in charge will ensure that obtaining the TCLE (Annex 1) is conducted in accordance with the specifications and international regulatory requirements of the ICH (International *Council for Humanization of Technical Requirements for Pharmaceuticals for Human Use)* for good clinical practices based on the ethical principles established by the resolution of the National Health Council (CNS, Resolution nº 466/2012).

be submitted to the CAPPesq Research Ethics Committee, via Plataforma Brasil. The ethical aspects of research involving human beings will be considered, as recommended by Resolution 466/2012. All data collected from volunteers will be treated ensuring confidentiality and meeting the other requirements established by the LGPD. The patients will be monitored by the multidisciplinary team via SI3, and any intercurrence verified by the multidisciplinary team in a " near real time" period and the patient will be consulted and guided in the face of the detected intercurrences.

After completing the survey, the data will be anonymized and analyzed by the InCor team. The raw data will be made available to the contracting company without any identification of the patient. After processing and analyzing the data, publication of the results in scientific databases is expected.

4. ESTIMATED SCHEDULE

ACTIVITIES	1st month	2nd month	3rd-7th month	8th month	9th month	10th-12th month
Clinical PT submission to the Scientific Committee and CAPPesq	x					
Analysis of the Clinical PT by the Research Ethics Committee	x	x				
Device Software Installation and Testing			x			
Execution of the Clinical Protocol (inclusion of patients and remote monitoring)			x			
Compilation and analysis of results				x		
Final report				x	x	
Accountability					x	
Submission of scientific articles						x

5. ANNEXES

5.1. Case Report Form (CRF)

CASE REPORT FORM

Study Title

***Wearable* -assisted digital telemonitoring of post-cardiovascular surgery patients**

Study Samsung FAPO-x

CLINICAL TRIAL/UNIT: INOVA InCor

PRINCIPAL INVESTIGATOR: Dr. Fabio Biscegli Jatene

EXECUTING RESEARCHER: Dr. _____

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

Investigator Signature: ----------

Patient Name

_____

Patient Signature:

_ ----------

Signing date:

D	d	m	m	m	Th	Th	Th	Th

Inclusion criteria		Yes	No
1	Is the subject older than 22 years old with heart disease ?		
2	Did the subject voluntarily give written informed consent?		
3	Does the subject agree to adhere to the study procedures?		
4	Does the subject have surgical indication in the presence of heart disease?		
5			

*If any inclusion criteria is marked as no, the patient is not eligible for the study.

Exclusion criteria		Yes*	No
1	Did the subject have post-surgical complications with an extension of the hospital stay for more than 14 days?		
2	Does the subject have any skin pathology or skin diseases? (ex : vitiligo, lupus and/or atopic dermatitis)		
3	Does the subject have allergies to the material components of the mobile device?		
4	Does the subject have significant abrasions on the body?		
5	For some reason did the patient not undergo cardiac surgery?		

VISIT 1 (TRIAGE)

Date: _____
DD MMM YYYY

INFORMED CONSENT

Note: Written informed consent must be given before any study-specific procedures occur or any current therapy is discontinued for the purposes of participation in this study.

Did the subject freely give written informed consent? Yes ☐ No ☐

DEMOGRAPHIC DATA

Age years): ☐☐ Fri: Feminine ☐ Masculine ☐

Height (m): ☐ • ☐☐

Weight (Kg): ☐☐ • ☐

BMI (BMI = Weight ÷ (Height × Height)): ☐☐ • ☐

Race:

Education Grade:

CLINICAL EVALUATION:

( ) Altered heart rhythm ( ) Signs of HF ( ) Dizziness/feeling faint

( ) Decrease in exercise tolerance, dyspnea ( ) Transient Ischemic Attack

( ) Stroke ( ) Chest pain ( ) Dyspnea at rest

( ) Exercise intolerance

Date of Symptom Onset: _____
DD MMM YYYY

other, please specify ---------- ----------

COMBITIES:

( ) Valvular Heart Disorder ( ) Diabetes Mellitus ( ) Hypertension
( ) COPD ( ) Hyperthyroidism ( ) TIA/CVA (history)
( ) Sudden cardiac death in FH

PREVIOUS PROCEDURES:

( ) No Procedures
( ) Coronary Angioplasty ( ) Revascularization Surgery ( ) Pacemaker
( ) Cardiac Resynchronization Therapy ( ) Valve Prosthesis
( ) Implantable cardiodefibrillator ( ) Ventricular Assist Device
( ) Heart Transplantation ( ) Chemical Cardioversion ( ) Electrical Cardioversion

SMOKING:

Yes ☐ No ☐

( ) Current *(Consumer for a period not less than 6 months)*
( ) Past *(If you have smoked at some point in your life, but have not smoked for more than 6 months)*

DRINKING:

Yes ☐ No ☐

( ) Current *(Consumer for a period not less than 6 months)*
( ) Past *(If you have smoked at some point in your life, but have not smoked for more than 6 months)*

The report or record of consumption of alcoholic beverages, alcoholism and/or alcohol intoxication will be considered in this study. According to the World Health Organization (WHO) acceptable consumption is up to: 15 drinks/week for men and 10 drinks/week for women

ILLICIT DRUGS :

Yes ☐ No ☐

Specify:

---------- ----------

PHYSICAL EXERCISE:

Yes ☐ No ☐

Specify:

---------- ----------

INGESTION OF MEDICINES

Is the subject currently or previously taking any medications, including vitamins and/or supplements?

Yes ☐ No ☐

* Record **all** medications on the Concomitant Medications page

MEDICAL HISTORY

Is there any relevant medical history on the following systems?

Code	System	*Yes	No	Code	System	*Yes	No
1	Cardiovascular			9	neoplasm		
two	Respiratory			10	Neurological		
3	Hepatobiliary			11	Psychological		
4	Gastrointestinal			12	Immunological		
5	genito-urinary			13	Dermatology		
6	Endocrine			14	allergies		
7	Hematological			15	Eyes, ear, nose, throat		
8	Skeletal muscle			00	Other		

** If **YES** to any of the above, please enter the code for each condition in the boxes below, provide further details (including dates) and indicate whether the condition is*

currently or potentially active. If providing details of surgery, specify underlying cause. Use a separate line for each condition.

		Currently active?	
Code	**Details (including dates)**	**Yes**	**No**

PHYSICAL EXAMINATION (To be performed only by the medical team)			
Code	**System**	***Not normal**	**Normal**
1	General appearance		
two	Cardiovascular		
3	Respiratory		
4	Gastrointestinal / Abdomen		
5	extremities		

* If **ABNORMAL** , enter the code for each condition in the boxes below and provide brief details. Please use one _ line separate for each condition .

Code	**Details**

VITAL SIGNS

Pulse ☐☐☐ bpm

Pressure Sanguine (sitting) ☐☐☐ / ☐☐☐ mmHg

ECG

Normal ☐ Not normal ☐ **

**
Description ____

( ) Sinus ( ) Atrial Fibrillation ( ) Atrial Flutter ( ) Nodal or Atrioventricular Reentry Tachycardia ( ) Wide QRS Tachycardia ( ) Bradyarrhythmias

Store the signed and dated dash in the plastic sleeve on the back of the CRF

LABORATORY ANALYSIS

Initials

Blood for hematology and biochemistry — harvested by ☐

✓		Collection Date (dd mmm yyyy)
	Hematology	
	Biochemistry	

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

CONCOMITANT MEDICATION

Medication	Daily Dose (total)	Items	Reason	Start date *(MM/DD/YYYY)*	End Date *(MM/DD/YYYY)*	Continuous
				___ ___/ ___ ___/ ___ ___ ___ ___	___ ___/ ___ ___/ ___ ___ ___ ___	☐
				___ ___/ ___ ___/ ___ ___ ___ ___	___ ___/ ___ ___/ ___ ___ ___ ___	☐
				___ ___/ ___ ___/ ___ ___ ___ ___	___ ___/ ___ ___/ ___ ___ ___ ___	☐
				___ ___/ ___ ___/ ___ ___ ___ ___	___ ___/ ___ ___/ ___ ___ ___ ___	☐
				___ ___/ ___ ___/ ___ ___ ___ ___	___ ___/ ___ ___/ ___ ___ ___ ___	☐
				___ ___/ ___ ___/ ___ ___ ___ ___	___ ___/ ___ ___/ ___ ___ ___ ___	☐
				___ ___/ ___ ___/ ___ ___ ___ ___	___ ___/ ___ ___/ ___ ___ ___ ___	☐

				___ ___ / ___ ___ / ___ ___ ___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	☐
				___ ___ / ___ ___ / ___ ___ ___ ___	___ ___ / ___ ___ / ___ ___ ___ ___	☐

Study End Date: ___ ___ / ___ ___ / ___ ___ ___ ___
(MM/DD/YYYY)

STUDY CLOSURE FORM

Reason for Terminating Study (Please tick main reason only. Reasons other than Completed Study require explanation next to answer)

☐ Study Concluded

☐ Adverse Event/Severe Adverse Event **(complete the Adverse Event form, if applicable)**

_____

☐ Lost to follow

_____

_____

☐ Participant no compatible

_____

_____

☐ Medication Concurrent

_____

_____

☐ Medication Contraindicated

_____

_____

☐ To remove consent

_____

_____

☐ Death __

_____

☐ Other

_____

_____

5. 2. Term of Loan Responsibility

I,_____, bearer of RG No._____UF _____, resident and domiciled at Address_____, No._____Bairro_____, City_____, State _____ Tel. With.: _____, Tel. Answer: _____.

I inform, for the due purposes, that I received from **INSTITUTO DO CORAÇÃO/FUNDAÇÃO ZERBINI** registered with CNPJ under no. 50.644.053/0001-13, the equipment described below, owned by **SAMSUNG ELETRÔNICA DA AMAZÔNIA LTDA** ., registered with CNPJ 23.209.756/0001-40, for exclusive use in the FAPO-X Samsung project of InovaInCor - InCor, for the term from 30 to 33 day(s) from this date, committing myself to return it in perfect condition at the end of this period.

I declare responsibility for their conservation, in accordance with the manufacturer's recommendations; committing myself not to lend or entrust to another person; and communicate, immediately to the **InovaInCor** via message to us **nº 11 XXXXXXXX, 11 XXXXXXXX** any incident and occurrence with the equipment(s); as well as ensuring the necessary precautions for the proper functioning and integrity of the assigned equipment, it being important to point out that the change of address (equipment) is not authorized without the knowledge and authorization of Inova InCor.

At the end of the monitoring period or, in case of withdrawal from the project, I will return the complete equipment and in perfect condition, considering the time of use, to the competent sector.

Gadgets	Model	Accessories	Serial number
Smartwatch galaxy 5		Induction Charger	
smartphone		USB Cable + Power Sup	

São Paulo, _____ of _____ of 20____

_____	_____
Studies Coordinator	Research Subject

5.3. Activity Diary

Notes until lunch			
Hour	Activities	Symptoms	Medicines

Notes after lunch until dinner			
Hour	Activities	Symptoms	Medicines

Notes after dinner (don't forget times you slept and woke up)			
Hour	Activities	Symptoms	Medicines

Time you slept: _____ Time you woke up: _____

Date	Hour	Symptoms (palpitations, chest pains, fainting, dizziness, vertigo, etc.)	Comments

Blood Pressure Monitoring					
Date	Hour	max	mine	Frequency	Therapy

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