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D4.3 Field trial design plan

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Authors: Peter Van Voorren (REM)

[1] L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario

[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

Partner list

Nr.	Partner name	Short name	Org. type	Country
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4	Remedus	REM	SME	Belgium
5	Seniornett Norge	SN	End-U	Norway
6	LifeonKey	LoK	SME	Israel
7	VigiSense S.A.	VIGS	SME	Switzerland
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9	Stichting Smart Homes	SmH	R&D	The Netherlands
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Revision history

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1.0	18/05/2018	FhP	Add protocol for field trial	Inês Lopes
1.1	15/06/2018	FhP	Review users' questionnaires, manuals and research questions	Inês Lopes
1.2	19/10	REM	Review research questions	Peter van Vooren
1.3	22/10/2018	FhP	Review research questions and add appendixes	Ines Lopes
1.4	25/10/2018	REM	Final review	Peter van Vooren

	25/10/2018	**Approved by FhP**

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1. Background

1.1. Introduction, scope and objectives of SmartBEAT

The SmartBEAT project aims to address the needs of senior Chronic Heart Failure (CHF) patients and their healthcare professionals and informal caregivers, by offering an integrated solution to leverage patient self-care through autonomous condition monitoring and real-time feedback to their caregivers. This objective will be achieved through remote measurement of patients' physiological data and a smartphone application integrated with a monitoring engine and a caregivers portal for data analysis, management and reporting.

In Figure 1, an overview is given of the SmartBEAT system for better orientation on the sections that will follow.

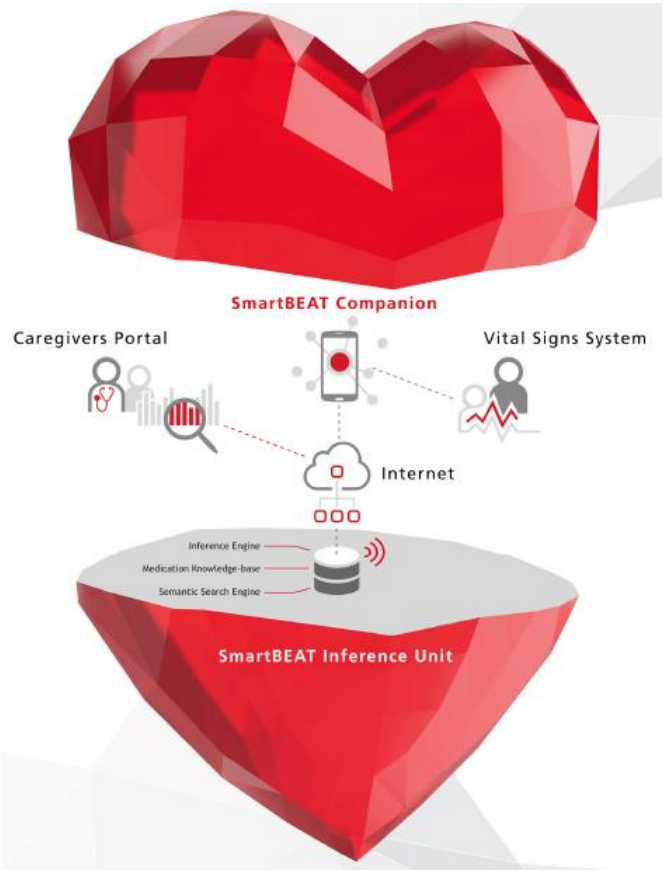


Figure 1 – SmartBEAT technology modules.

1.2. SmartBEAT components

In the field trial, the SmartBEAT prototype will be in its final stage. This implies that all features and specifications will be fully functional and integrated.

The features of each component are described very briefly below.

- **Vital Signs System (VSS)**

Sensor	Company	Name/model	Parameters
Weight scale	Yunmai	Mini Scale M1501	Weight, body fat, body water
Bracelet[3]	Xiaomi	Mi Band 2	HR, #steps, sleep tracker
Blood pressure monitor	Urion Technology Co.	U80E	Systolic BP, diastolic BP, HR
Oximeter	Jumper Medical Equipment Co.	JPD500F	SpO_2, HR

- **SmartBEAT Companion (SBC)**

  The SBC is an Android application that allows for the interaction between the user and the sensor devices, and for monitoring of HF-related signs and symptoms. It provides the following features:

  - Reminders and a user-friendly layout to perform the recommended measurement routine
  - It provides a questionnaire to monitor HF-related symptoms of decompensation
  - Graphical visualization of measured parameters
  - Reminders and registration of medication intake and doctor appointments
  - Motivational and coaching messages (associated with compliance)
  - Stores all measured parameters, including medication intake and questionnaires

- **Caregivers' Portal (CGP)**

  The SmartBEAT system provides two distinct portals. In the Netherlands and Belgium, the CGP is called *RemeCare* (developed by REM), and in Portugal and Norway is defined as *eHealthStudio* (developed by LoK).

  In both situations, healthcare professionals will be able to access patients' medical data, monitor patients' progress and visualize alerts. In addition, it will allow doctors and nurses to modify medication regimes and set appointments –when needed.

[3] For the pilot phase, the MioFuse – from Mio Global – was used. Due to connectivity, integration and usability issues, it was discontinued; and a new one was chosen. Please see D3.1/3.2 for more details on this decision.

- **Medical Inference Unit (MIU)**

  The Medical Inference Unit has two fundamental roles:

  (1) **Store and process data**

  It extracts data from the SBC, and makes it available for each CGP – RemeCare and LOK's eHealth Studio – to upload into their system. It is also in this module that specialized algorithms will process the acquired measurement data and compare it with baseline values of a specific patient, possibly giving rise to automatic alerts for therapeutic adjustments or notifications, according to the clinical status.

  (2) Knowledge base and semantic engine

  Depending on the user-group, it will provide different and specific features:

  - Care professionals: search relevant articles that match selected keywords using BioLabeler™ [4], and provide medical definitions of selected keywords from a Medical Dictionary – both in English only.
  - Patients and informal caregivers: search relevant articles and web pages related to selected keywords, using simple google search; and provide medical definitions according to a built-in glossary of terms[5].

[4] BioLabeler developed by Taniwa Solutions. See more at http://www.biolabeler.com/

[5] See D2.2 for Glossary of terms.

2. Purpose of the field trial

In WP4, the SmartBEAT system will be evaluated from a user perspective. To realize a high level of acceptance – for both senior CHF patients and healthcare professionals – the system needs to be attractive in terms of functionality, design and interaction.

Goal of the field trial is to evaluate usability and user satisfaction of the vital signs system (VSS) in combination with the SmartBEAT Companion (SBC) app to be used by senior CHF patients, and the Caregivers Portal (CGP) to be used by healthcare professionals, informal caregivers and CHF patients. Besides an intuitive and self-explanatory interface, the system should also fit in with existing infrastructure and current care processes in order to avoid mistakes and time loss.

Moreover, it should also demonstrate potential added value, in a way that the current care process could ideally improve and become faster – for example, by monitoring multiple patients at once and acting promptly at only those that are in imminent need of intervention. More importantly, it is of extremely importance that healthcare professionals believe in a system such as this, and that they are more efficient than in the current practice.

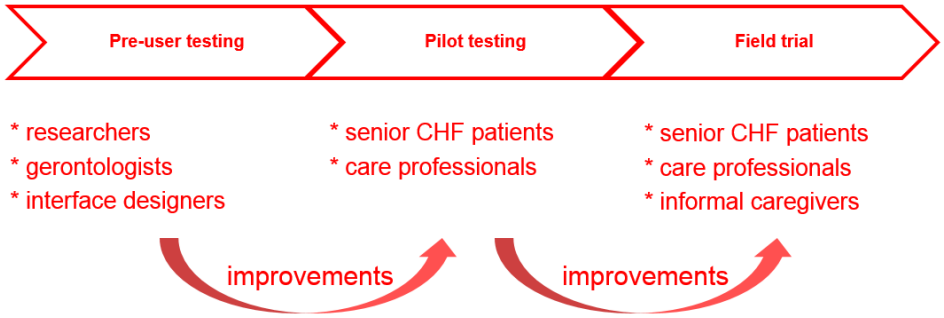


Figure 2 – WP4 evaluation phases.

2.1. Objectives of the field trial

Besides the more technical issues discussed above, the SmartBEAT technology and interfaces will be evaluated from a user point of view. Prior to this field trial, the SmartBEAT system was tested in a pilot setting as described in D4.1 Pilot Test Design Plan and D4.2 Pilot Evaluation Report.

During the field trial the SmartBEAT system will be evaluated by four groups of users in Portugal, Norway, Belgium and the Netherlands. These users will be primary users (CHF patients and their informal caregivers) and secondary users (healthcare professionals), with the eye on evaluating the experiences and perceptions of these users on the applicability of the SmartBEAT system before further clinical deployment in a setting with a much larger group of users.

- **Primary users: senior patients with CHF, class II and III**
  Objective of the field trial with senior patients is to assess usability and user satisfaction. Besides usual age-related changes, the SmartBEAT system also needs to take into account various disease-specific limitations. The protocol for user testing with patients is described in Chapter 6.

- **Primary users: informal caregivers**
  The participation of informal caregivers in the field trial phase will serve to assess, apart from the usability and user satisfaction evaluation, the increase in peace of mind (or ease of burden), and if the system is given as a power tool to better support their patients' – by means of educational material and others. The protocol for user testing with informal caregivers is defined in Chapter 6.
- **Secondary users: healthcare professionals**
  Besides primary end-users, the SmartBEAT system will be evaluated by secondary users – being healthcare professionals. Besides usability issues, efficiency and alignment with current care systems and care processes are of high importance. The protocol for user tests with healthcare professionals can be found in Chapter 7.

Based on the outcomes from the heuristic evaluation and pilot testing with real target subjects, the SmartBEAT system has been refined and the system has been updated accordingly as described in D3.4. The final SmartBEAT solution will now be evaluated by a larger group of CHF patients and their care network during a field trial between 1 to 3 months; in the natural environment and embedded in their daily routines. Metrics will be defined and applied to test the technology in daily living environment and circumstances. As tasks and responsibilities related to monitoring and intervening differ among different countries, evaluation processes in the field trial will be role-based rather than profession-based.

3. Overall research questions

The SmartBEAT field trial will be a first step in collecting information about perceptions from patients, healthcare professionals and informal caregivers. In order for telemonitoring to work out well, it is first of all important that both patients and healthcare professionals adhere to the system. Therefore, it is crucial that both user groups see more benefits than burden. To investigate this, the system needs to be used by a larger group of users for a longer time, embedded in their daily routines. For this, the field trial should be a combination of deployment and evaluation.

For the three groups of stakeholders, we will ask three primary research questions, related to:

1. Acceptance & usability of the SmartBEAT system
2. Perceived benefits by the primary and secondary users
3. Time consumption & planned adherence by the various groups of users

3.1. Research questions for senior CHF patients

3.1.1. Acceptance & Usability

In order to answer the primary research questions, a set of hypotheses are set up, to be tested in the field trial.

SRQ P1	**Acceptance** How well is SmartBEAT accepted by senior CHF patients?
Hypotheses: • H1.1 – SmartBEAT will get well accepted among senior CHF patients. • H1.2 – It is clear to the patient what is expected of him/her. • H1.3 – SmartBEAT works as expected.	
SRQ P2	**Usability** How easy is SmartBEAT to use by senior CHF patients?
Hypotheses: • H2.1 – SmartBEAT is easy to use. • H2.2 – SmartBEAT is easy to learn. • H2.3 – SmartBEAT is useful for managing my health.	

Table 1 – Research questions for CHF patients related to acceptance and usability

The hypotheses for acceptance and usability for senior CHF patients will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions and input throughout home-use (registering any contact made by the users).

3.1.2. Perceived benefits

In order to answer the primary research questions, a set of hypotheses are set up to be tested in the field trial.

SRQ P3	**Perceived health benefit** What is the effect of the SmartBEAT technology and services on the health status of senior CHF patients, and the way they deal with their condition?

Hypotheses:
• H3.1 – SmartBEAT will help CHF patients take better care of their health.
  ○ By early detection of health deterioration, exacerbations can be avoided.
  ○ By increasing medication adherence (reminders), exacerbations can be avoided.
  ○ By decreasing unplanned doctor visits and hospital admissions.
• H3.2 – SmartBEAT will increase self-management for senior CHF patients.
  ○ By providing monitoring tools and giving them access to their health data.
  ○ By using a reminder system to help them with medication and measuring adherence.
• H3.3 – Perceived impact on daily activities / quality of life	

SRQ P4	**Perceived Wellbeing** What is the effect of the SmartBEAT system on peace of mind, wellbeing, independence and feeling of safety and reassurance of senior CHF patients?

Hypotheses:
• H4.1 - SmartBEAT will increase peace of mind for senior CHF patients.
  ○ By being monitored to detect health deterioration in an early stage..
  ○ By getting coached in how to deal with their condition.
• H4.2 - Senior CHF patients will feel more safe and secure.
  ○ Knowing that they are kept an eye on by SmartBEAT in case of deviating measurements.
  ○ Knowing that they are supported by reminders in order to increase therapy adherence and consequently avoiding health deterioration.	

Table 2 – Research questions for CHF patients related to perceived benefits

The hypotheses for perceived health benefit and wellbeing for senior CHF patients will be tested with a questionnaire which assesses 'usability' and 'perceptions', and a Quality of Life questionnaire (EQ-5D-3L) These quantitative outcomes will be complemented with experimenters' notes from test sessions and input throughout home-use (registering any contact made by the users).

3.1.3. Time consumption and planned adherence

In order to answer the primary research questions, a set of hypotheses are set up to be tested in the field trial.

SRQ P5	**Time consumption and perceived burden** How much time do senior CHF patients spend on taking the SmartBEAT measurements and how do they feel about it?

Hypotheses:
• H5.1 - Senior CHF patients will only spend little time on operating the SmartBEAT system.
  ○ By presenting the measurements in a daily ritual, they will get used to it quickly.
  ○ By configuring/personalizing the monitoring regime, the requested effort will decrease.
• H5.2 - Senior CHF patients will not experience the daily measurements as a heavy burden.
  ○ By using an easy interface that facilitates quick completion.
  ○ By making the system attractive in terms of functionality and design.
  ○ By giving them valuable feedback and coaching.	

SRQ P6	**Planned adherence** Do senior CHF patients envisage to continue using the system for a period longer than the duration of the field trial?
Hypotheses: • H6.1 – Senior CHF patients will continue to use the SmartBEAT in the future. • H6.2 – Senior CHF patients performed routine every day.	

Table 3 – Research questions for CHF patients related to time consumption and planned adherence

The hypotheses for time consumption and planned adherence for senior CHF patients will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions and input throughout home-use (registering any contact made by the users).

3.2. Research questions for informal caregivers

3.2.1. Acceptance & Usability

In order to answer the primary research questions, a set of hypotheses are set up, to be tested in the field trial.

SRQ I1	**Acceptance** How well is SmartBEAT accepted by informal caregivers?
Hypotheses: • H1.1 – SmartBEAT is well accepted among informal caregivers. . • H1.2 – SmartBEAT works as expected.	
SRQ I2	**Usability** How easy is SmartBEAT to use by informal caregivers?
Hypotheses: • H2.1 – SmartBEAT is easy to use. • H2.2 – SmartBEAT is easy to learn. • H2.3 – SmartBEAT is useful.	

Table 4 – Research questions for informal caregivers related to acceptance and usability

The hypotheses for acceptance and usability for informal caregivers will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions (pre and post home-use).

3.2.2. Perceived benefits

In order to answer the primary research questions, a set of hypotheses are set up to be tested in the field trial.

SRQ I3	**Perceived health benefit** What is the perceived effect of the SmartBEAT technology and services on the health status of senior CHF patients, and the way the patients deal with their condition?

Hypotheses:
• H3.1 – Informal caregivers believe that senior CHF patients feel better.
  ○ By early detection of health deterioration, exacerbations can be avoided.
  ○ By increasing medication adherence (reminders), exacerbations can be avoided.
  ○ By decreasing unplanned doctor visits and hospital admissions.	

• H3.2 – SmartBEAT helps informal caregivers take better care of CHF patients. ○ By providing monitoring tools and giving them access to their health data. • H3.3 – Informal caregivers observe an impact on daily activities/QoL of CHF patients.	
SRQ I4	**Perceived Wellbeing** What is the effect of the SmartBEAT system on peace of mind, wellbeing, independence and feeling of safety and reassurance of informal caregivers?

Hypotheses:
• H4.1 - SmartBEAT will increase peace of mind for informal caregivers.
  ○ By being monitored to detect health deterioration of CHF patients in an early stage.
• H4.2 – The SmartBEAT system lowers the burden on informal caregivers.
  ○ By using a reminder system to help senior CHF patients with therapy adherence.
  ○ By allowing the CHF patients to take their own measurements and perform their own registrations.
• H4.3 – Informal caregivers perceive that senior CHF patients feel more safe and secure.
  ○ Knowing that they are kept an eye on by SmartBEAT in case of deviating measurements.
  ○ Knowing that they are supported by reminders in order to increase therapy adherence and consequently avoiding health deterioration.
  ○ Knowing that personal data is stored securely.	

Table 5 – Research questions for informal caregivers related to perceived benefits

The hypotheses for perceived health benefits and wellbeing for informal caregivers will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions (pre and post home-use).

3.2.3. Time consumption and planned adherence

In order to answer the primary research questions, a set hypotheses are set up to be tested in the field trial.

SRQ I5	**Time consumption and perceived burden** How much time do informal caregivers spend on the SmartBEAT system and does the SmartBEAT system reduce their burden of care?

Hypotheses:
• H5.1 – Informal caregivers will only spend little time on helping CHF patients operating the SmartBEAT system.
• H5.2 – Informal caregivers perceive that using SmartBEAT will take little time for CHF patients.
• H5.3 – SmartBEAT will decrease the burden of care for informal caregivers
  ○ By realizing self-management, less support is needed from informal caregivers.
  ○ By providing sufficient support on how to use the system.	

SRQ I6	**Planned adherence** Do informal caregivers envisage to continue using the system for a period longer than the duration of the field trial?
Hypotheses: • H6.1 – Informal caregivers would like to help CHF patients use SmartBEAT in the future. • H6.2 – Informal caregivers would like for CHF patients to use SmartBEAT in the future.	

Table 6 – Research questions for informal caregivers related to time consumption and planned adherence

The hypotheses for time consumption, perceived burden and planned adherence for informal caregivers will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions (pre and post home-use).

3.3. Research questions for healthcare professionals

3.3.1. Acceptance & Usability

In order to answer the primary research questions, a set of hypotheses are set up to be tested in the field trial.

SRQ H1	**Acceptance** How well is the SmartBEAT system accepted by healthcare professionals?
Hypotheses: • H1.1 – SmartBEAT is well accepted among healthcare professionals. • H1.2 – SmartBEAT works as expected.	
SRQ H2	**Usability** How easy is SmartBEAT to use by healthcare professionals?
Hypotheses: • H2.1 – SmartBEAT is easy to use. • H2.2 – SmartBEAT is easy to learn. • H2.3 – SmartBEAT is useful.	

Table 7 – Research questions for healthcare professionals related to time consumption and planned adherence

The hypotheses for acceptance and usability for healthcare professionals will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions (pre and post portal use) and during portal use.

3.3.2. Perceived benefits

In order to answer the primary research questions, a set of hypotheses are set up, to be tested in the field trial.

SRQ H3	**Perceived Quality of Care** To what extent can SmartBEAT increase quality of care?

Hypotheses:
• H3.1 - SmartBEAT provides a clear and more complete picture of the health status of a patient.
  ○ By combining a collection of objective health measurements with more subjective prompts.
  ○ By having larger collections of longitudinal measurement data (daily monitoring).
  ○ By being able to see in a glance how the older adult is doing.
  ○ By presenting alerts and changes in patients' vital signs in a personalized news feed.
• H3.2 - SmartBEAT makes care decisions easier
  ○ By having all information you need.
  ○ By early detection of change in health.
  ○ By being able to take the appropriate action at the appropriate time.	

SRQ H4	**Perceived Efficiency of care** To what extent can SmartBEAT increase efficiency of care?

Hypotheses:
• H4.1 - SmartBEAT will provide all information in one place.
  ○ By being able to see in a glance how the senior CHF patient is doing.
  ○ By providing healthcare professionals with a personalized news feed, which will highlight important events such as alerts and changes in patients' vital signs.
• H4.2 - SmartBEAT will decrease the burden of care for healthcare professionals.
  ○ By realizing self-management, less support is needed from healthcare professionals. Senior CHF patients can take measurements themselves using a set of telemonitoring devices capable of recording physiological data measurements to adequately monitor their health status.
  ○ By automating certain tasks. The system intelligence contains specialized algorithms that will process the acquired measurement data and compare these data with baseline values of the specific patient, possibly giving rise to automatic alerts for therapeutic adjustments or notifications, according to the clinical status.	

• H4.3 - SmartBEAT offers significant added value for healthcare professionals.
  ○ By providing a useful dashboard with an overall view on the health status of the CHF patient.
  ○ By providing alerts to healthcare professionals only when required and by not providing unnecessary alerts.

Table 8 – Research questions for healthcare professionals related to perceived benefits

The hypotheses for perceived quality and efficiency of care for healthcare professionals will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions (pre and post portal use) and during portal use.

3.3.3. Time consumption and planned adherence

In order to answer the primary research questions, a set of hypotheses are set up to be tested in the field trial.

SRQ H6	**Time consumption and perceived burden** How much time do healthcare professionals spend on working with the SmartBEAT system and how do they feel about it?

Hypotheses:
• H6.1 – Healthcare professionals will only spend little time on operating the SmartBEAT system.
  ○ By presenting the measurements in a daily ritual, they will get used to it quickly.
• H6.2 – Healthcare professionals will not experience the SmartBEAT system as a heavy burden.
  ○ By using an intuitive graphical user interface.
  ○ By making the system attractive in terms of functionality and design.
  ○ By giving them valuable feedback and information.	

SRQ H7	**Planned adherence** Do healthcare professionals envisage to continue using the system for a period longer than the duration of the field trial?
Hypotheses: • H7.1 – Healthcare professionals would like to use SmartBEAT in the future.	

Table 9 – Research questions for healthcare professionals related to time consumption and planned adherence

The hypotheses for time consumption, perceived burden and planned adherence for health care professionals will be tested with a questionnaire which assesses 'usability' and 'perceptions', completed with experimenters' notes from test sessions (pre and post portal use) and during portal use.

4. Measurements methods

The field trials with CHF patients are dedicated to the evaluation of the SmartBEAT technology, including the SmartBEAT Companion app and the sensor devices from the vital signs system. The field trial consists of 1 to 3 months testing at home.

During this period, patients will use the SmartBEAT Companion (SBC) app and Vital Signs System (VSS) at home, doing a daily morning ritual. The goal is to evaluate the (technical) performance and the user acceptance of the system, and to check the perceived benefits of the patients, informal caregivers and healthcare professionals involved. After this testing period, each patient, each informal caregiver and each healthcare professional is requested to fill out a questionnaire to evaluate user experience and effort of the daily process. Each individual user will be asked to participate in a telephone/or in-person interview to assess the use of the SmartBEAT system.

This section lists and describes the measurement methods, questionnaires and/or interview questions used for the primary (senior CHF patients and informal caregivers) and secondary users (healthcare professionals).

4.1. Questionnaires and assessments for senior CHF patients

Patients will perform two questionnaires: one focused on the quality of life experience with symptoms (QL-5D-3L) and another on usability and overall perceptions. In addition, CHF patients will be subjected to a very brief cardiac evaluation. The questionnaires and cardiac evaluation will be executed before and after the field trial phase (see Appendix 8.3, 8.5).

4.2. Questionnaires for informal caregivers

Informal caregivers will perform one questionnaire to evaluate usability and overall perceptions. The questionnaire will be done before and after the field trial phase (see Appendix 8.4, 8.6).

4.3. Questionnaires for healthcare professionals

Care professionals will be subjected to a short questionnaire with a 5-point likert scale before and after the field trial phase (see Appendix 8.9-10).

5. Field Trial Planning

Before starting the field trials in the different countries, it is important to carefully plan field trial operations, define workflows and protocols, distribute tasks and develop materials. In this chapter, field trial preparation is described on a general project level. More details on operational planning in each individual field trial site, can be found in D5.5.

5.1. Collaborative workflow and local task distribution

For the trials to be successful, all procedures, activities and materials need to be well-prepared. Parts will be organized on a central level for all trial sites, but other aspects need to be prepared and organized locally.

CENTRAL LEVEL

As the overall field trial procedure is similar in all four sites, and the field trial has a limited scale, we believe in organizing different key parts on a central level. To realize this, the consortium needs to designate:

- **Central system manager:**
  Filipe Sousa – Fraunhofer Portugal – filipe.sousa@fraunhofer.pt
  Responsible for establishing operational continuity of the SmartBEAT system, including system performance monitoring, maintenance, updates, database serving, and security.
- **Central evaluation manager**
  Peter Van Vooren – Remedus – peter.vanvooren@remedus.be
  Responsible for the overall evaluation strategy and planning, and alignment of the local evaluation activities in the different sites.

SITE LEVEL

Whereas some aspects can be organized centrally, many tasks need to take place at location. From this perspective, different local teams need to be set up in each individual site, collaborating under supervision of a local site manager. It is imperative that all these parties clearly understand their specific responsibilities and assignments in preparation and implementation of the field trial.

Although there are many different tasks, the number of people that have direct contact with the field trial participants should be limited, to not hamper the stability of the home environment. As the field trial has a limited scale, some persons might take up different tasks. This can be decided on local site level.

- **Local site manager**
  Responsible for the total execution of the field trial in one specific trial site, managing the work of the different local teams in line with the overarching procedures, and reporting back to the central level managers. Together with representatives of the teams below, the local site manager is responsible for quality assurance; overseeing day-to-day operations concerning trial preparation and execution. In this view, helpdesk issues and technical

monitoring outcomes will be discussed and documented in detail to improve helpdesk intervention, education and technical infrastructure.
In addition, the local site manager is first contact point for healthcare professionals in terms of explanation of project and system procedures, training and helpdesk. A fully operational helpdesk is unnecessary and little efficient for a small group of system users.

- **Local technical team**
  One or more technicians that are responsible for local technical issues concerning system monitoring performance and troubleshoot during the field trial. In addition, the technical team acts as second line helpdesk support for both patients and professionals.
  As the SmartBEAT solution is a smartphone application with a set of Bluetooth peripheral devices, no physical home installation is required. Each SmartBEAT set can be prepared in advance by the technical team, so that only the connection with the in-home WiFi network needs to be established on-site.
- **Local recruitment team**
  One or more medical staff members that are responsible for the local recruitment process. The recruitment team selects patients according to the defined inclusion criteria, informs them about the project, asks for their willingness to participate, and take care of filling in the informed consents.
- **Local interaction team**
  One or more project staff persons responsible for all project-related interaction with patients and informal caregivers[6] in one trial site. This team is responsible for configuration of the system (account settings and contact details), delivery of the SmartBEAT set and connection to the home WiFi network, training, first-line helpdesk and evaluation activities with both patients and informal caregivers[6]. The latter will be motivated to be closely involved in the intake process and training, being one unit together with the patient. In the evaluation, both perspectives need to be handled separately.

5.2. Healthcare professional training and protocols

For the SmartBEAT system to be successfully implemented, the field trials need support of experienced and well-trained healthcare professionals. They need to be explained what protocols to follow, and how to use the SmartBEAT caregivers portal.

- **RemeCare Portal – CGP to be used in Belgium and the Netherlands**
  Remedus will develop specific training material (PowerPoint presentation) that outlines how to use the CGP, with a step-by-step description of the complete process, starting with the inclusion of a new patient, overview of the various screens and possible notifications, followed by all the different actions and decisions the care professional

[6] Norway will not include informal caregivers.

should register and, finally, how a patient can leave the project, e.g. at the end of the field trial.
Remedus will organise two training sessions; the first one in Belgium for the heart failure nurses and cardiologists in the ZOL hospital in Genk, and the second one for the general practitioners and general practice-based nurse specialists in Eindhoven, the Netherlands.

- **eHealthStudio – CGP to be used in Portugal and Norway**
  LoK will develop specific training material (PowerPoint presentation) that outlines how to use the CGP, with a step-by-step description of the complete process, starting with the inclusion of a new patient, overview of the various screens and possible notifications, followed by all the different actions and decisions the care professional should register and, finally, how a patient can leave the project, e.g. at the end of the field trial.

Each site will select 10 patients to be included in the field trial. These patients will be asked to measure every day their vital signs and register their medication intake. In addition, these patients will be asked to answer a set of pre-defined questions every morning or when the SmartBEAT system detects deviating measurements. In Belgium and Portugal, cardiologists and heart failure nurses will monitor the health status of these patients from within the hospital. In the Netherlands, this task will be taken up by the general practitioner and general practice-based nurse specialist. In Norway, there will be no healthcare professionals' involvement.

The **care protocol** for healthcare professionals will be entirely focused on usability, acceptance and adherence. It is advised that any communication with the patients is registered and shall include for example difficulties, suggestions, complains, needs and doubts.

The access to the portal must be done daily, preferably in the afternoon (due to morning routine), and follow the steps below:

1. *Check for alerts*
   a. If there are specific alerts, verify the validity of the values and contact the patient to understand the context. If a medical intervention is required, and the contact point is a:
      i. Nurse, and the intervention is within the scope of the professional's duties; then the nurse must recommend an appointment and note down what the intervention would be (along with a justification). Otherwise, must be referred to a doctor.
      ii. Doctor, then the patient must be advised to schedule a medical appointment or go to a hospital. The doctor should note down, what the action it would have been done, if the system was operational in "real-life".
   b. If there are sensitive alerts, the contact point must note down the patient, in order to watch over the case in the following day.

2. *Verify that all patients are performing the measurements daily*. They should note down on an excel sheet the number of times patients are performing the measurements (and, if relevant, note down the context of repeated measurements – in a row or different periods of the day).
    a. If the patient did not miss, then no action is required.
    b. If the patient missed two days in a row, contact the patient to understand the reason for non-adherence.

5.3. Installation and configuration

Installation is conducted by the different local technical teams, and mainly consists of preparation of the individual SmartBEAT sets, which will consist of a smartphone with the SmartBEAT Companion (SBC) app pre-installed, and connected with the telemonitoring kit.

Before a SmartBEAT set is delivered to an individual patient, it needs to be ensured that Bluetooth pairing of all the measuring devices has been performed. To configure the SBC app, consequently, an account needs to be created and configured for each patient in the field trial, based on the input from the local interaction teams. Depending on the site, this configuration can be done either by the technical team or interaction team. In addition, the sets need to be delivered and connected to the home WiFi network (if applicable to the site), or alternatively the patient will do the installation at home.

To make sure that all systems work properly and configuration is done correctly and consistently across different sites, the local teams need to receive clear instructions. The instructions for each site are as follows:

Steps	**Instructions**
1	- Create 10 google accounts - Share the list of emails created with FhP in order to became a tester of the SBC app
2	- Create 10 smartbeat user accounts for patients - Create informal caregivers' credentials (if applicable) - Create user accounts' for healthcare professionals - Assign healthcare professionals to patients in the portal - Insert thresholds for each parameter (if applicable) and add the patient's medication plan (if available, otherwise update later on)
3	- Turn on all phones, login with the accounts created in step 1 and make sure: o Location is set to "High accuracy" o SIM card PIN is disabled (if applicable) o Play Store "Auto-update apps at any time" is selected. ▪ (Optional) To reduce data charges, disable automatic updates for all apps with the exception of SmartBEAT o Play Store notifications are turned OFF o Battery Power Saving mode is turned OFF o Screen timeout is set to "10 minutes" o Screen lock is set to "swipe"

4	- After FhP's confirmation, login into one account and go to: https://play.google.com/apps/testing/pt.fraunhofer.hfc.mobile.lifeonkey, and tap on "Become a tester". - Verify that "You are a tester" on the link above and then click on "Download the SmartBEAT Companion app on Google Play". - On Google Play, click on "Install" - Confirm that the app was installed on the phone logged in with that account. *Note: Do this for all of the accounts!*
5	- Log in with a patient's credentials - Grab a set of sensors and make sure you are isolated from other Bluetooth devices - Perform a daily routine but do not confirm the value. Also connect the bracelet. - Once the set of sensors is successfully connected, keep it away from the isolated place you are in. Repeat for all phones and kits!
6	- Charge all phones and bracelets.

5.4. Patient recruitment

Recruitment of patients will be conducted by each site-specific recruitment team and consists of several steps. The first step involves the definition of the target population (size, demographic characteristics, inclusion and exclusion criteria) and decisions concerning the method of sampling. Together with patient inclusion, we will try to involve informal caregivers in the intake procedure and training activities, in order for them to be able to offer hands-on support.

Below the eligibility criteria for screening potential participants.

Inclusion criteria
• Senior CHF patient (60+)* • NYHA class II or III • Regular use of smartphone • Having an informal caregiver who is willing to participate as well ** ** In Norway, the field trial will be executed with senior hypertension patients.* *** At least 50% of the patients must have an informal caregiver*
Exclusion criteria
• No internet access*

• Patient in institutional care • Physical, cognitive, sensorial and/or mental limitations that hinder them from using the technology or taking part in the evaluation activities ** Portugal and Belgium will provide SIM cards.*

Table 10 – Inclusion and exclusion criteria for patients taking part in the SmartBEAT field trial

The second step focuses on the identification of potentially eligible participants and explanation of the study. In each country, the local recruitment team either selects patients in daily practice or contacts potentially eligible CHF patients (from public records or project partner's registries). These patients are briefly introduced to the project. When they are interested, the local recruitment team provides them with a more detailed description of the SmartBEAT solution, of the planned evaluation activities, eventual benefits and risks involved, and how results will be evaluated. Patients must have all this information to be able to make an informed choice on whether or not to take part in the field trial. Next, a meeting will be scheduled, and an informed consent and pre-trial questionnaire will be delivered. Participants are asked to read and complete them at home and bring them in when they come for the next meeting.

In the third step, meetings will be organized with each patient individually, together with the informal caregiver (if applicable). One day before the scheduled meeting, the patient will be contacted by phone to confirm both interest and meeting time. Dependent on the local protocol, this meeting could be hosted by either the local recruitment team (contact person so far) or by the local interaction team (contact person from now on). During these individual meetings, the team

- Collects information about a patient's interests, needs and living context, in order to set-up the patient's account and configure the system accordingly.
- Investigates the possibilities of involving a patient's formal and informal caregiver in the field trial, so to setting up the social-medical support network around the patient.
- Provides information about the next steps to be taken.

For the field trial, the following patient information needs to be entered in the Remedus Care Givers Portal by a healthcare professional (nurse, GP or cardiologist). This information is collected from a pre-trial questionnaire:

- Personal details (see Appendix 8.3 – Identification)
- Clinical data (see Appendix 8.3 – Medical Information)

In addition, the system requires to enter the patient-specific notification thresholds for the vital signs.

Finally, to each patient the name of at least one physician and one nurse will be assigned. They will form the care team for a given patient. This will enable the healthcare professional to view only the patients assigned to him.

5.5. Patient training, support and helpdesk

All recruited patients will be trained prior to starting the field trials. The training phase will be conducted by each local interaction team and will aim at instructing and familiarizing patients with the SmartBEAT system and its different services. Individual training sessions will be planned and structured, based on the needs and objectives of those attending. Before the session, patients will be informed about the aim of the session, the learning outcome and the expected duration. Education will include information on how to use the smartphone, the SBC app and the various peripheral monitoring devices. A session involves demonstrations of the system – one guided and one autonomously. Also, informal caregivers will be invited to join the training, so to be able to support the person they are caring for in using the technology.

For the training sessions, training material will be prepared with clear explanations on how to use the SBC app and the different telemonitoring devices. For the field trial, also a helpdesk (call centre) will be in place in each site to answer questions and to provide (technical) support. The helpdesk will be accessible during office hours. When immediate problem solving seems to be impossible, the specific issue will be discussed with responsible technology providers (second line). The patient will be informed as soon as possible. All helpdesk issues will be documented in detail to improve helpdesk intervention, education and technical infrastructure.

The helpdesk is not for medical problems. In case of health-related issues, patients need to contact their GP, hospital or emergency services as they are used to.

6. Field trial protocol for patients and informal caregivers

In the following sections, the details of the protocol to be used for the field trial with the primary users, i.e. senior CHF patients and their informal caregivers, are described. In the field trial the Vital Signs System (VSS), the SmartBEAT Companion (SBC) app and the training material will be evaluated by the patient and the informal caregiver. The healthcare professionals will evaluate the Care Givers Portal (CGP). These field trials will be organized in Belgium, Portugal, the Netherlands and Norway.

6.1. Target group

The SmartBEAT project focuses on monitoring senior (65+) CHF patients; mainly NYHA classes II and III of the functional heart failure classification, representing the large majority of independent, ambulatory patients:

- **NYHA class II** – Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or dyspnoea (shortness of breath).
- **NYHA class III** – Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnoea (shortness of breath).

It is expected that these classes will benefit most from remote health monitoring and coaching. As NYHA class I patients are generally very stable, they would not benefit significantly from the proposed SmartBEAT solution. Patients from NYHA class IV, on the other hand, are normally severely decompensated and usually hospitalised.

In each field trial country – Belgium, Portugal, the Netherlands and Norway – ten patients are asked to participate in this activity on a voluntary basis, and can withdraw at any point in time without explanation. For the field trial, no experience with eHealth/mHealth technology is required, but some experience with pc, tablet or smartphone is recommended.

Below, the recruitment strategies in the different field trial countries are described:

- **Belgium**
  Remedus will recruit 10 senior (65+) CHF patients to participate in the field trial from its patient population. The patients will be NYHA class II patients with at least two months since their last CHF-related hospitalization and will be selected from those patients that visit the hospital for a consultation with their cardiologist. In addition, 5-10 informal caregivers or family members shall be recruited to provide support to the patient.
- **Portugal**
  10 stable CHF patients in NYHA class II or III will be recruited from an outpatient Heart Failure Clinic. In addition, 5-10 informal caregivers or family members shall be recruited to provide support to the patient.

- **Netherlands**
  SGE will recruit 10 stable CHF patients to participate in the field trial. The CHF senior patients will be recruited from the patients registered at the GP practices of SGE. These patients join a cardiovascular program at SGE. Three nurse practitioners of SGE will select the patients in consultation with the GP. In addition, 5-10 informal caregivers or family members shall be recruited to provide support to the patient.
- **Norway**
  Seniornett will recruit from its 1000 members in the Oslo area – mostly healthy elderly, but among them also persons suffering from heart problems. From personal knowledge, 10 persons from that group will be recruited: preferably CHF patients as defined above, but most probably hypertension patients. In addition, 5-10 informal caregivers or family members shall be recruited to provide support to the patient.

6.2. Procedure

The field trial consists of two parts. Firstly, patients are invited for a training session where patients are trained to use the SmartBEAT VSS and SBC, and evaluate both components and the user manual with a focus on usability. Secondly, patients use the SmartBEAT technology for a period of 1 to 3 months at home, to evaluate (technical) performance of the system on the one hand, and gain insight in the perceived benefits for the different groups of users on the other hand.

Preparation

At least two weeks before the start of the field trial, patients are informed in detail about the field trial goals and procedures. Also, it is scheduled the session with the patient and their informal caregiver (if possible).

Field trial – pre-test (training) session

For the field trial session, patients are welcomed and reminded about the goals and procedures, and their rights as field trial participants. They will also read and sign an informed consent form. During the training session, the SmartBEAT system with the SBC app and the VSS with the telemonitoring sensors are explained to the patient, along with the CGP platform (if applicable to the site). In addition, the patient and the informal caregiver are provided with a user guide that will serve as a reminder when these primary users wish to find extra information about the use of the SmartBEAT system.

At the end of the training session, the patients and informal caregivers are asked to fill out a small questionnaire concerning perceived usefulness, usability, perceived control, etc. (see Appendix 8.3-4).

To conclude the training session, patients receive an information sheet about the goals and the following steps within the SmartBEAT project, and take the sensor kit already configured and installed.

The patient training session will take approximately 45 minutes up to 1 hour in total.

Field trial – 1 to 3 months testing

During the home testing, there will be no contacts done by the medical team other than the ones specified in the care protocol.

Field trial – post-test session

One to two weeks before the home testing ends, a post-test session is scheduled with both patients and informal caregiver. Both will be requested to fill out a short questionnaire about their experiences using the SmartBEAT (see Appendix 8.5-6).

6.3. Data and analysis

Directly identifying information will be removed from the data and replaced by a participant code, to guarantee anonymous data analysis and representation. Confidential data will be stored in a safe or locked file cabinet, and handled only by authorized staff members.

Data from the field trial will be mainly used for internal reports. Some outcomes might be used for SmartBEAT dissemination, including Journal or Conference publications.

Quantitative and qualitative data from all different sources are merged into four country-specific field trial reports, in order to make proper analysis and interpretation. These data may include:

- Notes from experimenters with observations and quotes from patients
- Data from the self-administered questionnaires
- Sound/ image / video recordings

These country-specific field trial reports are combined, to check for similarities and differences across countries. In addition, the data from the self-administered questionnaires is put into a data sheet, and sent anonymously, in order to do cross-field trial comparison.

6.4. Experimenters / Interviewers

Experimenters are responsible for detailed observation and note taking during the test. Besides, they focus on instructions, questionnaires and tasks, and the equipment. To conclude, they have to combine all relevant findings in a report.

- ***Belgium:***
  For the field trial with the Belgian patients, there will be three experimenters: two project managers from Remedus and one researcher from Fraunhofer Portugal.
- ***Portugal:***
  The field trial with patients in Portugal will be organized by a team of three cardiologists (Prof. Silva Cardoso, Dr. Carla Sousa and Dr. Sérgio Leite) and one nurse with experience in technology support for seniors.
- ***Netherlands:***
  For the field trial in the Netherlands, there will be three experimenters: one project manager from SGE, one researcher from Smart Homes and one nurse practitioner from SGE. The responsible GP will be Dr. Ed Berends.
- ***Norway:***
  The field trial in Norway will be conducted by two persons from the Seniornett organization. One of them with strong technical background, both with long experience from taking part in testing of ICT / technical solutions.

6.5. Documents and materials

The following materials are prepared for the field trial session with senior CHF patients.

- **Informed consent + information for patients** *** appendix 8.1**
- **Informed consent + information form for informal caregivers** *** appendix 8.2**

- User manual for the SmartBEAT Companion app
- Instruction material for CGP (LoK and REM)
- Protocols for pre- and post-test sessions
- **Evaluation forms and questionnaires for patients (pre-test session)** *** appendix 8.3**
- **Evaluation questionnaire for informal caregivers (pre-test session)** *** appendix 8.4**
- **Evaluation forms and questionnaires for patients (post-test session)** *** appendix 8.5**
- **Evaluation questionnaire for informal caregivers (post-test session)** *** appendix 8.6**

- Word template to report on observations
- Excel data collection sheet

7. Field trial protocol healthcare professionals

In the following sections, details of the protocol used for the field trial with healthcare professionals are described. Since the healthcare professionals already have gained exposure to the CareGiver Portal (CGP) during the pilot test, these healthcare professionals will only be asked to give their formal feedback on the use of the SmartBEAT system through a short questionnaire and feedback collected throughout the duration of the field trial.

To showcase the integration possibilities with different care professional systems, two different CareGiver Portals will be used. In Belgium and the Netherlands, healthcare professionals will evaluate the Remedus CGP, and in Portugal and Norway the CGP from LifeOnKey.

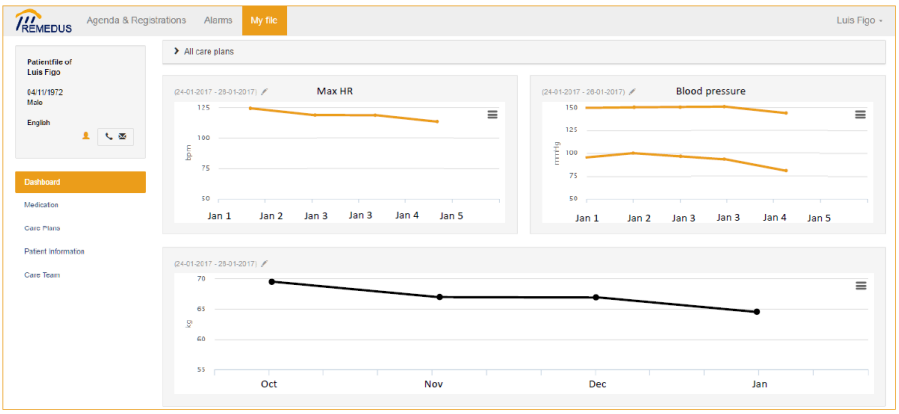


Figure 3 – SmartBEAT CGP Remedus.

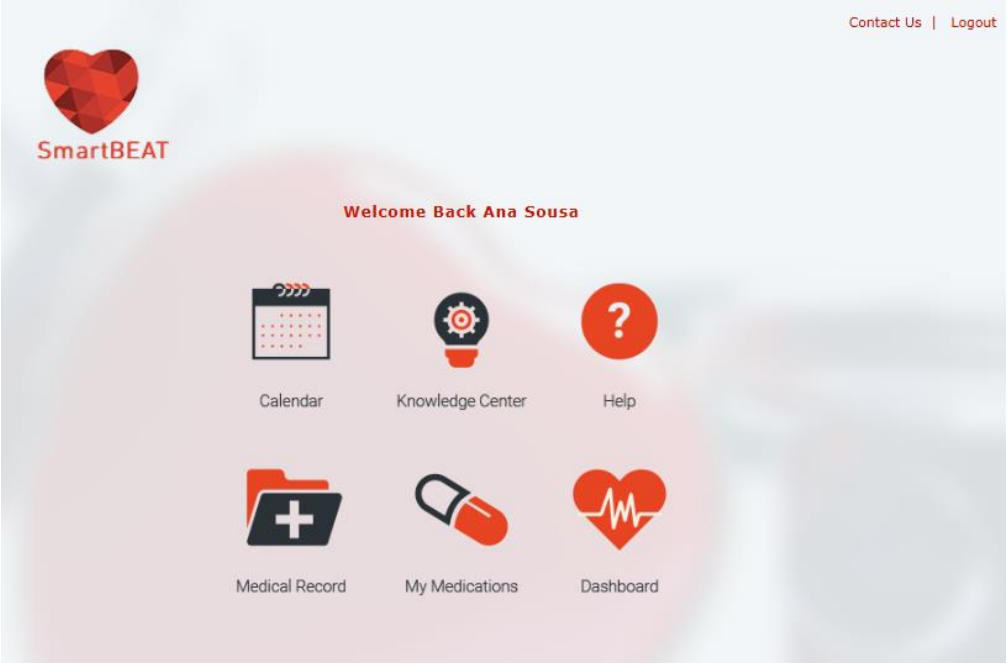


Figure 4 – SmartBEAT CGP LifeOnKey.

7.1. Target groups

The SmartBEAT project focuses on monitoring senior CHF patients. In this, a variety of professional caregivers is involved, ranging from cardiologists and heart failure nurses, GP's, and care managers. In the four field trial countries, different types of healthcare professionals will be involved. Below, the recruitment strategies are described:

- ***Portugal:***
  FhP has identified 3 cardiologists and 1 nurse to participate in the field trial. All work at the HF outpatient clinic of the Central Hospital of São João. The nurse will work under the supervision of the 3 cardiologists.
- ***Norway:***
  Not applicable.
- ***Belgium:***
  Remedus has already identified three heart failure nurses to participate in the field trial. All three work with CHF patients at the cardiology department of the ZOL hospital in Genk. All heart failure nurses work under the supervision of a cardiologist.
- ***Netherlands:***
  SGE has asked three nurse practitioners, who run the cardiovascular program at SGE, to participate in the field trial. The nurse practitioner will involve their GP in the project. The cardiology network in Eindhoven (Maxima Medical Center, Catharina Hospital and Anna Hospital) is informed.

7.2. Procedure

The SmartBEAT system provides functionality for the senior CHF patient on the one hand, and for the care professional on the other hand. For the professional, following subjects play an important part: access to up-to-date patient information, data exchange and communication among other healthcare professionals, and interaction with the patient.

In order to avoid mistakes and time loss, the SmartBEAT system needs to be as reliable and user-friendly as possible. The system should be self-explanatory to keep the learning curve low, and it should fit current care processes.

The aim of the field trial is gathering a deeper insight in:

- Perceived usability and acceptance of the platform
- Perceived quality of care and efficiency of care
- Time consumption and planned adherence

Field trial – CGP training session for the healthcare professionals

The field trials with healthcare professionals are dedicated to the evaluation of the SmartBEAT CareGiver Portal. At first, a short demo is organized to show the updated portal and its new or

enhanced functionalities. Secondly, professionals shall receive a short training on the use of the SmartBEAT CareGiver Portal. During this CGP training session, the SmartBEAT system and the CareGiver Portal are explained to the healthcare professionals. These healthcare professionals are provided with a user guide.

The field trial training session will take approximately 30 minutes as these healthcare professionals had previous exposure to the SmartBEAT system during the pilot tests.

Finally, healthcare professionals will be subjected to a pre-test questionnaire (see Appendix 8.9).

Field trial – 1 to 3 months testing

During the training sessions, the healthcare professionals will enroll 10 patients in each country and they will use the CareGivers Portal during this period, on a regular basis, according to specifications of the care protocol (see Section 5.2).

At the end of the field trial, the experimenters will provide a questionnaire with a 5-point likert scale and a free-text field for completion (see Appendix 8.10).

7.3. Data and analysis

Directly identifying information is removed from the data and replaced by a participant code, to guarantee anonymous data analysis and representation. Confidential data will be stored in a safe or locked file cabinet, and handled only by authorized staff members.

Data from the field trial will be mainly used for internal reports. Some outcomes might be used for SmartBEAT dissemination, including Journal or Conference publications.

Country by country, quantitative and qualitative data from the different sources are merged into one country-specific field trial report, in order to make proper analysis and interpretation. These data include:

- Notes from experimenters with observations and quotes from healthcare professionals
- Data from the self-administered questionnaires
- Sound/ image / video recordings

Afterwards, the three different reports are combined, to compare the experiences.

7.4. Experimenters / Interviewers

The experimenters focus on instructions, questionnaires and tasks, and equipment. In addition, the experimenters do observations and pose some extra questions during system use. To conclude, the experimenters combine all relevant findings in a report.

- ***Portugal:***
  The field trial with cardiologists in Portugal will be conducted by one project manager and two researchers researcher.
- ***Belgium:***
  For the field trial with Belgian healthcare professionals (three heart failure nurses), there will be three experimenters: two project managers from Remedus and one researcher from Fraunhofer Portugal.
- ***Netherlands:***
  For the field trial in the Netherlands, there will be three experimenters: one project manager from SGE, one researcher from Smart Homes and one nurse practitioner from SGE. The responsible GP will be Dr. Ed Berends.

7.5. Documents and materials

The following materials are prepared for the field trial session with healthcare professionals.

- ***Project information flyer for healthcare professionals*** **** appendix 8.7***
- ***Informed consent form for healthcare professionals*** **** appendix 8.8***

- *Instruction material for CGP (LoK and REM)*
- ***Evaluation questionnaire for healthcare professionals (pre-test)*** **** appendix 8.9***
- ***Evaluation questionnaire for healthcare professionals (post-test)*** **** appendix 8.10***

- *Word template to report on observations*
- *Excel data collection sheet*

8. Appendices

Appendix 8.1 – Project information + informed consent patients

SmartBEAT project

"Informative sheet"

Title of the project: SmartBEAT
Coordinator: Fraunhofer, Portugal
Interaction team: Name (Organization); Name (Organization)
Contact: #contact number 1 (Person's name); #contact number 2 (Person's name);
Location: [session location]
[Study approved by the Ethical Committee for Health, ref [#], on [date]]

Project aim: This study has the goal to identify problems associated with Heart Failure, as well as to develop and test a smartphone app that will allow for the monitoring of HF-related symptoms by the patient and their carer/family member. In this phase, the goal is to test the telemonitoring system in respect to its functionality, ease of use and comfort. Furthermore, it shall be identified positive aspects and difficulties of its use.

Methodology: The telemonitoring system for Heart Failure shall be used every day at home, during [X months], by participants diagnosed with Heart Failure and also healthy seniors to realize technological challenges related to ageing. The participants will be evaluated before and after the use of the SmartBEAT system, by means of sessions, to investigate health status, quality of life and perceptions related to the technology. The sessions shall be recorded in audio format, for transcription and analysis, and later on destroyed.

Benefits: By participating in this study, you will contribute to a better understanding of Heart Failure and to the development of a Heart Failure self-management strategy, which may in the future benefit you and others. All assessment and intervention procedures are considered safe and uncomfortable.

Type of participation: The participants of this study will be asked initially to carry out an evaluation of their health status, quality of life and the use of SmartBEAT, in the context of a test session.
After receiving training in the use of the Telemonitoring System for Heart Failure, you will be asked to use this system at home for X months. During this time, they should use the system daily to assess their weight, blood pressure, oxygen saturation, and heart failure related symptoms every day. The system automatically captures the participant's information and sends it to a portal. At the end, a new evaluation of the health status, quality of life and the use of SmartBEAT will be carried out in the context of a test session.
Your participation is voluntary and you may leave the study at any time, for any reason, with no consequence or prejudice for future treatment. Use of SmartBEAT does not alter or replace any usual medical care. As such, you should follow scheduled medical treatments and use routine and / or emergency medical services as you usually do or if you need to.

Confidentiality, privacy and anonymity: The information collected during the study is confidential and will be entered into a database, with identifiable data being encrypted and not accessible for purposes other than those of this investigation. Personal and health information built into the smartphone will be erased from the mobile phone and the server after being encrypted and analysed in an anonymous and confidential database. Recordings in audio format may be interrupted or deleted when the participant wishes and they will be destroyed after transcription.

I accept that SmartBEAT sessions are recorded in audio format? S|__| N|__|

SmartBEAT project

"Informed consent"

Study Designation
SmartBEAT Field Trial

I confirm that I have explained to the participant, in an appropriate and understandable manner, the research study, the benefits, risks and possible complications associated with its realization.

Information attached: ☐ No ☒ Yes (No. of pages 1)

Participant Identification

Name: _____

Identification Number: _____

Participant

- I understood the explanation given to me about the study I intend to carry out: the objectives, methods, expected benefits, potential risks and possible discomfort.
- I asked for all the information I needed, knowing that clarification is key to a good decision.
- I have been informed of the possibility of freely refusing or abandoning participation in the study at any time, without prejudice to the assistance given.

I agree to the participation in this study, according to the clarifications given to me, as it appears in this document, from which I received a copy.

Date: ____/____/____ _____

signature

Appendix 8.2 – Project information + informed consent Informal Caregivers

SmartBEAT project

"Informative sheet"

Title of the project: SmartBEAT
Coordinator: Fraunhofer, Portugal
Interaction team: Name (Organization); Name (Organization)
Contact: #contact number 1 (Person's name); #contact number 2 (Person's name);
Location: [session location]
[Study approved by the Ethical Committee for Health, ref [#], on [date]]

Project aim: This study has the goal to identify problems associated with Heart Failure, as well as to develop and test a smartphone app that will allow for the monitoring of HF-related symptoms by the patient and their carer/family member. In this phase, the goal is to test the telemonitoring system in respect to its functionality, ease of use and comfort. Furthermore, it shall be identified positive aspects and difficulties of its use.

Methodology: The telemonitoring system for Heart Failure shall be used every day at home, during [X months], by participants diagnosed with Heart Failure and also healthy seniors to realize technological challenges related to ageing. Each participant shall choose to be accompanied by an informal caregiver or a family member.
The informal caregiver/family member will be evaluated before and after the use of the SmartBEAT system, by means of sessions, to investigate their own and their patients' perceived perceptions. The sessions, performed with the patient, shall be recorded in audio format, for transcription and analysis, and later on destroyed.

Benefits: By participating in this study, you will contribute to a better understanding of Heart Failure and to the development of a Heart Failure self-management strategy, which may in the future benefit you and others. All assessment and intervention procedures are considered safe and uncomfortable.

Type of participation: The participants of this study will be asked to accompany the patient during the patient's evaluation and fill out a questionnaire of their initial perceived perceptions on SmartBEAT.
After receiving training in the use of the SmartBEAT App and the Care Givers Portal, you will be asked to support the patient whenever needed and monitor the patient with Portal. At the end, a new evaluation of their own and their patients' perceived perceptions on the use of the system.
Your participation is voluntary and you may leave the study at any time, for any reason, with no consequence or prejudice for future treatment. Use of SmartBEAT does not alter or replace any usual medical care. As such, it should be followed scheduled medical treatments and routine and/or emergency medical services as you usually do or if you need to.

Confidentiality, privacy and anonymity: The information collected during the study is confidential and will be entered into a database, with identifiable data being encrypted and not accessible for purposes other than those of this investigation. Recordings in audio format may be interrupted or deleted when the participant wishes and they will be destroyed after transcription.

I accept that SmartBEAT sessions are recorded in audio format? S|__| N|__|

SmartBEAT project

"Informed consent"

Study Designation
SmartBEAT Field Trial – Informal Caregiver

I confirm that I have explained to the participant, in an appropriate and understandable manner, the research study, the benefits, risks and possible complications associated with its realization.

Information attached: ☐ No ☒ Yes (No. of pages 1)

Participant Identification

Name: _____

Identification Number: _____

Participant

- I understood the explanation given to me about the study I intend to participate: the objectives, methods, expected benefits, potential risks and possible discomfort.
- I asked for all the information I needed, knowing that clarification is key to a good decision.
- I have been informed of the possibility of freely refusing or abandoning participation in the study at any time, without prejudice to the assistance given.

I agree to the participation in this study, according to the clarifications given to me, as it appears in this document, from which I received a copy.

Date: ____/____/____ _____
signature

Appendix 8.3 – Patient questionnaire (Pre-Session)

*SmartBEAT Field Test * Pre-Test*

PERSONAL INFORMATION – PATIENT & INFORMAL CAREGIVER

Date ___/___/___

Participation number: _____
Tel: _____ **Location:** _____ **Email:** _____

CONCLUDED THE STUDY? Y_1 N_0 **Date:** ___/___/___

DROPOUT? Y_1 N_0 **Date:** ___/___/___ **Reason:** _____

IDENTIFICATION

1. Genre: Female |__|$_0$ Male |__|$_1$ **2. Date of Birth:** ____/____/_____

3. Marital status: |__|$_1$ Married/Non-marital partnership |__|$_2$ Single |__|$_3$ Widower |__|$_4$ Separated/Divorced

4. Education: number of full years: ____ years

PROFESSIONAL AND FAMILY SITUATION

1. Professional situation
Active worker $_1$|__| Retired, not active $_2$|__| Retired, active $_3$|__| Unemployed/Sick leave $_4$|__| Domestic $_5$|__| Other $_6$|__| _____

2. Occupation (before several occupations choose the most important or longest): _____

3. Lives where: House |__|$_1$ Nursing home |__|$_2$ Another situation |__|$_4$ Specify: _____

4. Lives with: Alone |__|$_1$ Life partner |__|$_2$ Other relatives |__|$_3$ Another situation |__|$_4$ Specify: _____

INFORMAL CAREGIVER

1. Informal Caregiver participates in the study? Y_1 N_0
Relationship: _____
Lives with the participant? Y_1 N_0 Frequency of contacts (number of days/~~week~~) _____
Genre: Female $_0$|__| ~~Male~~ $_1$|__| Age: _____ Education: _____ (number of full years) Occupation: _____

Obs1.: Observations on sociodemographic data

MEDICAL INFORMATION (Silva-Cardoso et al., 2018)

A. CHARACTERIZATION OF THE HEALTH STATUS TO THE OBSERVATION DATE

1. Main chronic disease:

None |__|$_1$

Hypertension |__|$_2$

Heart Failure |__|$_3$ NYHA Class (current): $_1$**I** ____ $_2$**II** ____ $_3$**III**____

Other |__|$_4$ Specify: _____

2. Weight (weight scale): _____kg **Height:** _____ cm **BMI:** _____ kg.m^{-2}

3. Heart rate (BP monitor) : _____ bpm

4. Blood pressure (BP monitor) : ____/____ mm Hg

5. Oxygen Saturation (oximeter) : _____ %

B. THERAPEUTICS - PHARMACEUTICALS

Pharmaceuticals (insert name)	Dose (mg)				
	Day	Morning	Lunch	Afternoon	Night
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____
_____	____	____	____	____	____

Obs.2:

USABILITY AND PERCEPTIONS ABOUT SMARTBEAT - PATIENT

1. SmartBEAT Use - Observation

Instruction: *Please try SmartBEAT, as if you were using it in your home. We will ask you to try it by yourself, but your [caregiver] or we can help if necessary. We'll ask you to start by turning on your mobile phone, clicking the SmartBEAT icon, and then following the monitoring steps, until the end. We will ask you to read the instructions aloud.*

May we proceed? Y_1 N_0

[The material will be on the table and the weight scale will already be place in a stable position]

A. SmartBEAT routine	By himself	Minimal help [a]	Great help [a]	Does not do	Observations (mistakes, difficulties, strategies)	Type of help
Turn on the smartphone						
Insert the PIN code (if applicable)						
Look for the SmartBEAT app						
Open the SmartBEAT app						
1. Weight Scale						
1.1. Tap on the "Weight Scale" item						
1.2. Read the instructions out-loud						
1.3. Remove your shoes and socks						
1.4. Wait for the instruction to step on the weight scale						
1.5. Stay stable on the weight scale and wait until the numbers appear on the screen						
1.7. Read the value on the screen and try to interpret it						
1.8. Get off the weight scale						
1.9. Tap "Confirm" and go to the next step						
2. Oxygen saturation						
2.1. Tap on the "Oxygen Saturation" item						
2.2. Read the instructions out-loud						
2.3. Sit and try to relax						
2.4. Tap "Next"						
2.5. Open the oximeter correctly						
2.6. Place your index finger in the oximeter cavity						
2.7. Keep your finger stable inside the oximeter on top of the table						
2.8. Turn on the oximeter on the central button						
2.9. Keep the finger stable after turning it on						
2.10. Tap "Next"						
2.11. Wait until the number and the message "Confirm" appear on the screen						
2.12. Remove the finger from the oximeter						
2.14. Tap "Confirm" and go to the next step						
3. Blood Pressure						
3.1. Tap on the "Blood Pressure" item						
3.2. Read the instructions out-loud						
3.3. Sit and try to relax						
3.4. Keep your feet on the ground and lean back on the chair						
3.5. Tap "Next"						
3.6. Pull/Remove your clothes to keep your left arm ready for the measurement						
3.6. Place the cuff on the left arm with the tube next to the bend of the elbow						
3.7. Turn on the BP monitor, tapping only one time on the start/stop button						
3.8. Check if the number is blinking						
3.9. Keep your left arm stable						
3.10. Tap "Next"						
3.11. Wait until the cuff starts to insufflate						
3.12. The cuff should be adjusted to the arm but without squeezing too much during insufflation						
3.13. Wait until the numbers and the message "Confirm" appears on the screen						
3.14. Read the values out-loud						
3.15. Try to interpret/identify each value						
3.16. Tap "Confirm" and go to the next step						
4. Questionnaire						
4.1. Tap on the "Questionnaire" item						
4.2. Follow the questions						
5. Bracelet						
5.1. Wear the bracelet						
5.2. Tap on the "Bracelet" icon						
5.3. Wait until synchronization is complete						

[a] Minimal help: only one to two verbal instructions by the carer or the evaluator per sensor;

B. SmartBEAT History	By himself	Minimal help a)	Great help b)	Does not do	Observations (mistakes, difficulties, strategies)	Type of help
Tap on the left-side menu						
Tap on "History"						
1. Weight						
1.1. Tap on the "Weight Scale" icon"						
1.2. Interpret the graph						
2. Oxygen Saturation						
2.1. Tap on the "Oxygen Saturation" icon"						
2.2. Interpret the graph						
3. Blood pressure						
3.1. Tap on the "Blood Pressure" icon"						
3.2. Interpret the graph						
4. Physical Activity (Steps)						
4.1. Tap on the "Steps" icon"						
4.2. Interpret the graph						
5. Heart Rate						
5.1. Tap on the "Heart Rate" icon						
5.2. Interpret the graph						

C. Prescribed Medication	By himself	Minimal help)	Great help)	Observations (mistakes, difficulties, strategies)	Type of help
Tap on the left-side menu					
Tap on "Medication"					
Interpret the information displayed					

Obs3.: Observations on Usability

QUALITY OF LIFE EQ-5D-3L

Overall, how do you feel today?
Mark with a cross (X), a square of each of the following groups, indicating which of the statements best describes **your state of health today**.

EQ5D.1. Mobility

1. I have no problems in walking about. ☐
2. I have some problems in walking about ☐
3. I am confined in bed ☐

EQ5D.2. Personal cares

1. I have no problem with self-care ☐
2. I have some problems washing or dressing myself ☐
3. I am unable to wash or dress myself ☐

EQ5D.3. Usual activities (e.g. work, study, housework, family or leisure activities)

1. I have no problems with performing my usual activities ☐
2. I have some problems with performing my usual activities ☐
3. I am unable to perform my usual activities ☐

EQ5D.4. Pain / Unwellness

1. I have no pain or discomfort ☐
2. I have moderate pain or discomfort ☐
3. I have extreme pain or discomfort ☐

EQ5D.5. Anxiety / Depression

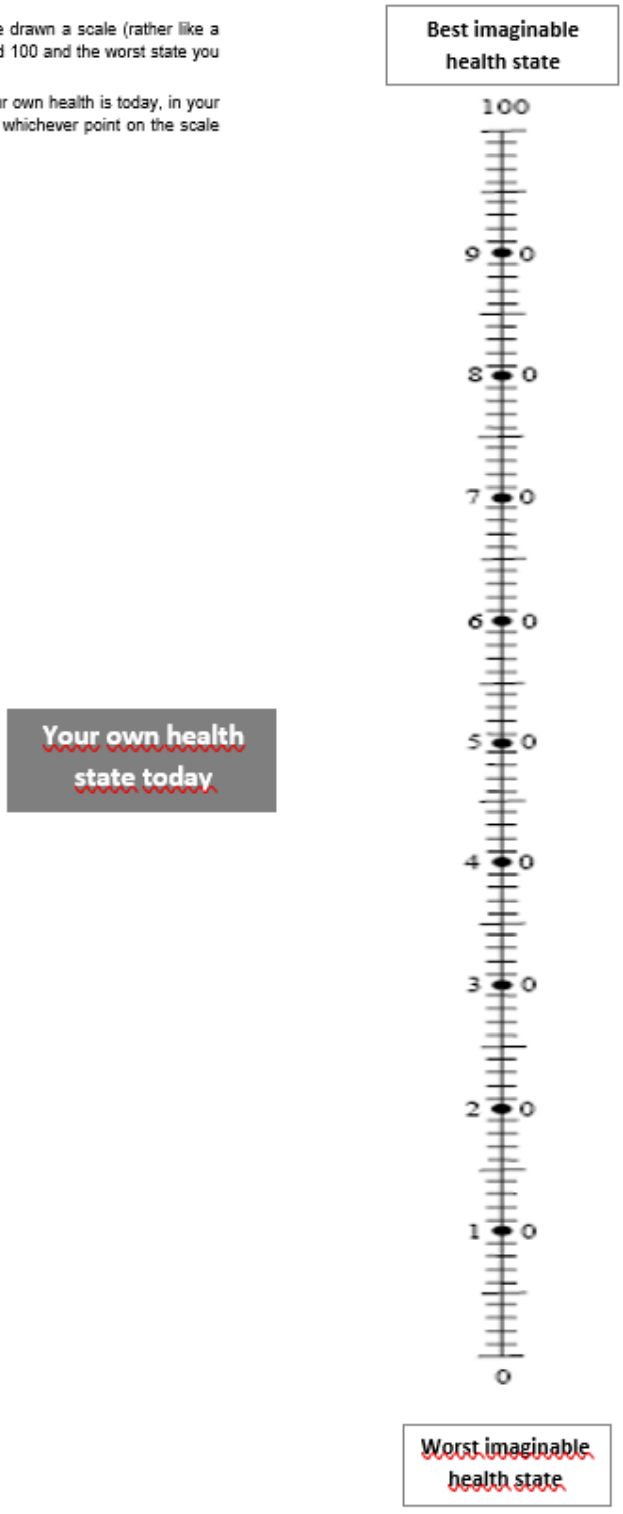
1. I am not anxious or depressed ☐
2. I am moderately anxious or depressed ☐
3. I am extremely anxious or depressed ☐

EQ-5D-3L: _____

QUALITY OF LIFE EQ-5D-3L (UK version, continuation)

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



7

USABILITY AND PERCEPTIONS ABOUT SMARTBEAT – PATIENT (Moreira et al., 2018)

Instruction: *Although we have tried SmartBEAT just now, we would love to hear from you about this technology. Below there is a set of sentences with SmartBEAT opinions. Please respond to the extent to which you agree / disagree with the following statements, based on your opinion of SmartBEAT. Circle the number that best indicates your opinion.*

As explained before we will record this part of the session. Do you agree? **Y_1** **N_0**

Strongly disagree	Disagree	Do not agree Do not disagree	Agree	Strongly agree
1	2	3	4	5

1. SmartBEAT is **easy** to use.	1	2	3	4	5
2. SmartBEAT is **useful for taking care of my health.**	1	2	3	4	5
3. It was **easy to learn** how to use SmartBEAT.	1	2	3	4	5
4. SmartBEAT **works well.**	1	2	3	4	5
5. I will **use** SmartBEAT at home.	1	2	3	4	5
6. I will use SmartBEAT **every day.**	1	2	3	4	5
7. Using SmartBEAT will **take up a lot of time** (average daily time: _____).	1	2	3	4	5
8. Using SmartBEAT will help me **feel better on a daily basis.**	1	2	3	4	5
9. Using SmartBEAT will help me **take better care of my health.**	1	2	3	4	5
10. Using SmartBEAT will help me **better control** my illness (heart failure)	1	2	3	4	5
11. I will feel **safer on a day-to-day basis** when using SmartBEAT.	1	2	3	4	5

Obs4. Observations/comments on usability – Patients

_____
_____
_____
_____
_____
_____
_____
_____
_____

Suggestions of improvements to SmartBEAT

_____
_____
_____
_____
_____
_____

Appendix 8.4 – Informal Caregiver questionnaire (Pre-session)

USABILITY AND PERCEPTIONS ABOUT SMARTBEAT – INFORMAL CAREGIVER (Moreira et al., 2018)

Instructions: *Although we have tried SmartBEAT just now, we would love to hear from you about this technology. Below there is a set of sentences with SmartBEAT opinions. Please respond to the extent to which you agree / disagree with the following statements, based on your opinion of SmartBEAT. Circle the number that best indicates your opinion.*

As explained before we will record this part of the session. Do you agree? **Y_1** **N_0**

Auto-fill |__| **Assisted filling |__|**

Strongly disagree	Disagree	Do not agree Do not disagree	Agree	Strongly agree
1	2	3	4	5

1. SmartBEAT is **easy** to use.	1	2	3	4	5
2. SmartBEAT is **useful** for taking care of my patient/family member's health.	1	2	3	4	5
3. It was easy for my patient/family member **to learn** how to use SmartBEAT.	1	2	3	4	5
4. SmartBEAT **works well**.	1	2	3	4	5
5. My patient/family member will use SmartBEAT at home.	1	2	3	4	5
6. My patient/family member will use SmartBEAT **every day**.	1	2	3	4	5
7. Using SmartBEAT will **take up a lot of time** for my relative (average daily time: _____).	1	2	3	4	5
8. Helping my patient/family member to use SmartBEAT will **take up a lot of time**.	1	2	3	4	5
9. Using SmartBEAT will **help my patient/family member feel better** on a daily basis.	1	2	3	4	5
10. Using SmartBEAT will help me **take better care of my patient/family member's health**.	1	2	3	4	5
11. Using SmartBEAT will help **me better control my patient/family member's illness** (heart failure)	1	2	3	4	5
12. My patient/family member will feel **more secure on a day-to-day basis** when using SmartBEAT.	1	2	3	4	5
13. I will **feel calmer** because my patient/family member uses SmartBEAT.	1	2	3	4	5
14. SmartBEAT will help **reduce my stress** when taking care of my relative.	1	2	3	4	5

The carer will help the patient in the daily routine of SmartBEAT? **Y_1** **N_0**

Type of help expected to be given: _____

Obs5. Observations/comments on usability – Informal caregivers

_____
_____
_____
_____
_____
_____
_____
_____

Suggestions of improvements to SmartBEAT

_____
_____
_____
_____
_____

9

Appendix 8.5 – Patient questionnaire (Post-Session)l

*SmartBEAT Field Test * Post-Test*

MEDICAL INFORMATION (Silva-Cardoso et al., 2018)

A. CHARACTERIZATION OF THE HEALTH STATUS TO THE OBSERVATION DATE

1. **Weight** (weight scale): _____kg **Height:** _____ cm **BMI:** _____ $kg.m^{-2}$
2. **Heart rate** (BP monitor): _____ bpm
3. **Blood pressure** (BP monitor): ____/____ mm Hg
4. **Oxygen Saturation** (oximeter): _____ %

Obs 6.:

*SmartBEAT Field Test * Post-Test*

QUALITY OF LIFE EQ-5D-3L (UK version)

Date ____/____/____

Overall, how do you feel today?
Mark with a cross (X), a square of each of the following groups, indicating which of the statements best describes **your health status today.**

EQ5D.1. Mobility

1. I have no problem walking. ☐
2. I have some problems walking ☐
3. I must stay in bed ☐

EQ5D.2. Personal cares

1. I have no problem with my personal care ☐
2. I have some problems washing me or getting dressed ☐
3. I am unable to wash or dress myself ☐

EQ5D.3. Usual activities *(e.g. work, studies, domestic activities, family or leisure activities)*

1. I have no problem performing my usual activities ☐
2. I have some problems to perform my usual activities ☐
3. I am unable to perform my usual activities ☐

EQ5D.4. Pain / Unwellness

1. I have no pain or discomfort ☐
2. I have moderate pain or discomfort ☐
3. I have extreme pain or discomfort ☐

EQ5D. Anxiety / Depression

1. I am not anxious or depressed ☐
2. I am moderately anxious or depressed ☐
3. I am extremely anxious or depressed ☐

EQ-5D-3L: _____

QUALITY OF LIFE EQ-5D-3L (UK version, continuation)

To help people say how good or bad their health status is, we've designed a scale (similar to a thermometer) in which the best health status imaginable is scored as 100 and the worst state you can imagine is scored as 0.

We would like you to indicate on this scale, how good or bad, in your opinion, **your health status is today**. Please draw a line from the square below to the point on the scale that best describes your health status today.

USABILITY AND PERCEPTIONS ABOUT SMARTBEAT - PATIENT (Moreira et al., 2018)

Instruction: *Although we have tried SmartBEAT just now, we would love to hear from you about this technology. Below there is a set of sentences with SmartBEAT opinions. Please respond to the extent to which you agree / disagree with the following statements, based on your opinion of SmartBEAT. Circle the number that best indicates your opinion.*
As explained before we will record this part of the session. Do you agree? **Y_1** **N_0**

Auto-fill |__| **Assisted filling |__|**

Strongly disagree	Disagree	Do not agree Do not disagree	Agree	Strongly agree
1	2	3	4	5

1. SmartBEAT is **easy** to use.	1	2	3	4	5
2. SmartBEAT is **useful for taking care of my health.**	1	2	3	4	5
3. It was **easy to learn** how to use SmartBEAT.	1	2	3	4	5
4. SmartBEAT **works well.**	1	2	3	4	5
5. **I was able to use SmartBEAT at home**.	1	2	3	4	5
6. I was able to use SmartBEAT every day.	1	2	3	4	5
7. Using SmartBEAT took up a lot of time. (average daily time: _____).	1	2	3	4	5
8. Using SmartBEAT has helped me **feel better on a daily basis**.	1	2	3	4	5
9. Using SmartBEAT helped me **take better care of my health**.	1	2	3	4	5
10. Using SmartBEAT helped me **better control my illness (heart failure)**.	1	2	3	4	5
11. I felt **safer on a day-to-day basis when using SmartBEAT**.	1	2	3	4	5
12. I would like to use SmartBEAT in the future.	1	2	3	4	5

Obs7. Observations/comments on usability – Patients

_____
_____
_____
_____
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_____
_____
_____

Suggestions of improvements to SmartBEAT_____
_____
_____
_____
_____
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_____
_____

Appendix 8.6 – Informal Caregiver questionnaire (Post-Session)

USABILITY AND PERCEPTIONS ABOUT SMARTBEAT – INFORMAL CAREGIVER (Moreira et al., 2018)

Instruction: *Although we have tried SmartBEAT just now, we would love to hear from you about this technology. Below there is a set of sentences with SmartBEAT opinions. Please respond to the extent to which you agree / disagree with the following statements, based on your opinion of SmartBEAT. Circle the number that best indicates your opinion.*
As explained before we will record this part of the session. Do you agree? **Y_1** **N_0**

Auto-fill |__| **Assisted filling |__|**

Strongly disagree	Disagree	Do not agree Do not disagree	Agree	Strongly agree
1	2	3	4	5

1. SmartBEAT is **easy** to use.	1	2	3	4	5
2. SmartBEAT is **useful for taking care** of my patient/family member's health.	1	2	3	4	5
3. It was **easy** for my family member to **learn** how to use SmartBEAT.	1	2	3	4	5
4. SmartBEAT **works well**.	1	2	3	4	5
5. My patient/family member **was able to use** SmartBEAT at home.	1	2	3	4	5
6. My patient/family member was able to use SmartBEAT **every day**.	1	2	3	4	5
7. Using SmartBEAT took a lot of time for my **patient/family member**. (average daily time: _____).	1	2	3	4	5
8. **Helping** my patient/family member use SmartBEAT **has taken a lot of time** (average daily time: _____).	1	2	3	4	5
8. Using SmartBEAT has helped my patient/family member feel better on a daily basis.	1	2	3	4	5
9. Using SmartBEAT helped me **take better care of my patient/family member's health**.	1	2	3	4	5
10. Using SmartBEAT helped to better **control my patient/family member's illness (heart failure).**	1	2	3	4	5
11. My patient/family member **felt safer on a day-to-day basis** when using SmartBEAT.	1	2	3	4	5
12. I **felt calmer** while my patient/family member was using SmartBEAT.	1	2	3	4	5
13. SmartBEAT has helped **reduce my stress** when taking care of my patient/family member.	1	2	3	4	5
14. **In the future,** I would like to continue helping my patient/family member use SmartBEAT (if required).	1	2	3	4	5
15. **In the future,** I would like my patient/family member to use SmartBEAT.	1	2	3	4	5

Obs8. Observations/comments on usability – Informal Caregivers

_____
_____
_____
_____
_____
_____
_____
_____
_____

Suggestions of improvements to SmartBEAT _____
_____
_____
_____
_____
_____
_____

Appendix 8.7 – Care professional Project Information flyer

SmartBEAT project

"Informative sheet"

Title of the project: SmartBEAT
Coordinator: Fraunhofer, Portugal
Interaction team: Name (Organization); Name (Organization)
Contact: #contact number 1 (Person's name); #contact number 2 (Person's name);
Location: [session location]
[Study approved by the Ethical Committee for Health, ref [#], on [date]]

Project aim: This study has the goal to identify problems associated with Heart Failure, as well as to develop and test a smartphone app that will allow for the monitoring of HF-related symptoms by the patient and their carer/family member. In this phase, the goal is to test the telemonitoring system in respect to its functionality, ease of use and burden.

Methodology: The SmartBEAT system shall be used every day at home, during [X months], by Heart failure patients and also healthy seniors to realize technological challenges related to ageing. Moreover, healthcare professionals shall monitor, daily, the existence of alerts from monitored participants.
Healthcare professionals will be evaluated before and after the use of the SmartBEAT system, by means of sessions, to investigate overall perceptions, acceptance and user-friendliness of the system. It will also be asked to healthcare professionals to record any contact with patients, and their adherence to the system.

Benefits: By participating in this study, you will contribute to a better understanding of Heart Failure and to the development of a Heart Failure self-management strategy, which may in the future benefit both HF patients and healthcare professionals. All assessment and intervention procedures are considered safe and uncomfortable.

Type of participation: The healthcare professionals of this study will be asked initially to carry out a demonstration of the Caregivers Portal, proceeded by a short questionnaire to evaluate overall perceptions, acceptance and user-friendliness of the system.
After receiving training in the use of the Caregivers Portal, it will be asked to use this system at daily for X months. During this time, it shall be recorded the adherence of the patient, the quality and quantity of the alerts generated and record any contact made with the patient. At the end, it shall be filled a questionnaire to evaluate, once again, overall perceptions, acceptance and user-friendliness of the system.
Your participation is voluntary and you may leave the study at any time, for any reason, with no consequence or prejudice for future treatment.

Confidentiality, privacy and anonymity: The information collected during the study is confidential and will be inserted into a database, with identifiable data being encrypted and not accessible for purposes other than those of this investigation. Personal information existing in the Portal, and recorded data will be erased after being encrypted and analysed in an anonymous and confidential database.

Appendix 8.8 – Care professional Informed Consent

SmartBEAT project

"Informed consent"

Study Designation
SmartBEAT Field Trial – Healthcare professionals

I confirm that I have explained to the participant, in an appropriate and understandable manner, the research study, the benefits, risks and possible complications associated with its realization.

Information attached: ☐ No ☒ Yes (No. of pages 1)

Participant Identification

Name: _____

Identification Number: _____

Participant

- I understood the explanation given to me about the study I intend to participate: the objectives, methods, expected benefits, potential risks and possible discomfort.
- I asked for all the information I needed, knowing that clarification is key to a good decision.
- I have been informed of the possibility of freely refusing or abandoning participation in the study at any time, without prejudice to the assistance given.

I agree to the participation in this study, according to the clarifications given to me, as it appears in this document, from which I received a copy.

Date: ____/____/____ _____
signature

Appendix 8.9 – Care Professionals questionnaire (Pre-Session)

SMARTBEAT FIELD TEST

PRE-TEST

PERCEPTIONS ABOUT SMARTBEAT – HEALTH PROFESSIONALS

Instruction: *Please answer to the extent to which you agree/disagree with the following statements, based on your opinion of SmartBEAT. Circle the number that best indicates your opinion.*

Strongly disagree	I disagree	I do not agree I do not disagree	I agree	Strongly agree
1	2	3	4	5

1. SmartBEAT is **easy** to use.	1	2	3	4	5
2. SmartBEAT is **useful for HF patients to care** for **their health.**	1	2	3	4	5
3. It is **easy** for HF patients to **learn how** to use SmartBEAT.	1	2	3	4	5
4. SmartBEAT **works well.**	1	2	3	4	5
5. HF Patients **will use** SmartBEAT at home.	1	2	3	4	5
6. HF Patients will use SmartBEAT **every day.**	1	2	3	4	5
7. Using SmartBEAT will **occupy** a lot of the **patient's time** (Average daily time: _____).	1	2	3	4	5
8. Using SmartBEAT will help HF patients **to feel better** in their daily lives.	1	2	3	4	5
9. Using SmartBEAT will help HF patients **to improve their health care.**	1	2	3	4	5
10. Using SmartBEAT will help HF patients **to better control heart failure.**	1	2	3	4	5
11. HF patients will feel **more secure on a day-to-day basis** when using SmartBEAT.	1	2	3	4	5
12. **Informal caregivers** will **feel calmer** while using SmartBEAT.	1	2	3	4	5
13. SmartBEAT will help **reduce the burden on informal caregivers.**	1	2	3	4	5
14. Monitoring HF patients using SmartBEAT's CGP will take **a lot of my time** (Average daily time: ___	1	2	3	4	5
15. SmartBEAT will **give me additional and useful information** about my HF patients.	1	2	3	4	5
16. SmartBEAT will be a **useful health management tool** for my HF patients	1	2	3	4	5
17. SmartBEAT will help me in **clinical-decision making** regarding HF patients.	1	2	3	4	5
18. SmartBEAT will help patients **improve adherence to therapy.**	1	2	3	4	5
19. I will use SmartBEAT as a **working tool in my clinical practice.**	1	2	3	4	5
20. I believe that SmartBEAT will contribute to a **more effective and efficient clinical management** of HF.	1	2	3	4	5

Obs1. Observations/comments

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Suggestions of improvements to SmartBEAT _____

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Appendix 8.10 – Care Professionals questionnaire (Post-Session)

POST-TEST

PERCEPTIONS ABOUT SMARTBEAT – HEALTH PROFESSIONALS

Instruction: Please answer to the extent to which you agree/disagree with the following statements, based on your opinion of SmartBEAT. Circle the number that best indicates your opinion.

	Strongly disagree	I disagree	I do not agree I do not disagree	I agree	Strongly agree

SmartBEAT is **easy** to use.	1	2	3	4	5
2. SmartBEAT is **useful for HF patients to take care of their health.**	1	2	3	4	5
3. It is **easy** for HF patients to **learn how** to use SmartBEAT.	1	2	3	4	5
4. SmartBEAT **works well.**	1	2	3	4	5
5. Most HF patients **managed to use** SmartBEAT at home.	1	2	3	4	5
6. Most HF patients managed to use SmartBEAT **every day.**	1	2	3	4	5
7. Using SmartBEAT **occupied a lot of time to the patient** (Average daily time: _____).	1	2	3	4	5
8. Using SmartBEAT helped HF patients **to feel better** in their daily lives.	1	2	3	4	5
9. Using SmartBEAT helped HF patients to **improve their health care.**	1	2	3	4	5
10. Using SmartBEAT helped HF patients to **control heart failure better.**	1	2	3	4	5
11. HF Patients feel **safer on a day-to-day basis** when using SmartBEAT.	1	2	3	4	5
12. **Informal caregivers felt more relaxed** when using SmartBEAT.	1	2	3	4	5
13. SmartBEAT has helped to **reduce the burden on informal caregivers.**	1	2	3	4	5
14. Monitoring HF patients using SmartBEAT's CGP took **time** (Average daily time: _____)	1	2	3	4	5
15. SmartBEAT gave me **information** about my HF patients.	1	2	3	4	5
16. SmartBEAT was a **useful** health **management tool** for my HF patients	1	2	3	4	5
17. SmartBEAT helped me in **clinical decision-making** for HF patients.	1	2	3	4	5
18. SmartBEAT helped patients **improve adherence to therapy.**	1	2	3	4	5
19. In the future, I will use SmartBEAT as a **working tool** in my clinical practice.	1	2	3	4	5
20. I believe that SmartBEAT will contribute to a **more effective and efficient clinical management** of HF cases.	1	2	3	4	5

Obs2. Observations/ comments

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Suggestions of improvements to SmartBEAT _____

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