D4.1   Pilot test design plan

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[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
1	Fraunhofer AICOS *(coordinator)*	FhP	R&D	Portugal
2	Centro Hospitalar São João	CHSJ	End-U	Portugal
3	Verhaert New Products & Services NV	VPS	SME	Belgium
4	Remedus	REM	SME	Belgium
5	Seniornett Norge	SN	End-U	Norway
6	LifeonKey	LoK	SME	Israel
7	VigiSense S.A.	VIGS	SME	Switzerland
8	The Eindhoven Corporation of Primary Health Care Centers	SGE	End-U	The Netherlands
9	Stichting Smart Homes	SmH	R&D	The Netherlands
10	Faculdade de Medicina Universidade do Porto	FMUP	R&D	Portugal

Revision history

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2	08/11/2016	SmH	Update based on GA in Tel Aviv	Wil Rijnen
3	19/01/2017	SmH	Update based on WP4 calls	Wil Rijnen
4	03/03/2017	SmH	Integration pilot-specific input and appendices	Mariëlle Nellen, Peter v Vooren, Helge Klitzing, Carla Sousa, Ines Lopes Sergio Leite, Filipe Sousa
5	16/03/2017	SmH	Finalisation	Wil Rijnen
6	26/03/2017	LOK, Rem	Internal Review	Linda Harnevo, Suzan Miller, Peter van Vooren
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| | 26/04/2017 | | **Approved by SmH** | |

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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 formal 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 smart phone application integrated with a monitoring engine and a caregivers portal for data analysis, management and reporting.

1.2.   SmartBEAT technology

The final SmartBEAT system will be a combination of different technologies. It will consist of the following modules:

1. **Vital Signs System (VSS):** a set of telemonitoring devices capable of recording physiological data measurements to adequately monitor the health status of CHF patients. It uses sensors and communication technologies for measuring several clinical variables considered essential by cardiologists.

   - **Continuous monitoring**
     - Heart rate
     - Physical activity
   - **Daily morning ritual**
     - Blood pressure
     - Heart rate in rest
     - Weight
     - Impedance
     - SPO2
     - Arrhythmia / irregular heart beat
   - **Questionnaire**

2. **SmartBEAT Companion (SBC):** a smart phone coaching app that provides a bridge between the VSS and the remaining components. The app is a user-friendly mobile solution that acts as a gateway and primary user interface for patients.

3. **SmartBEAT Inference Unit (MIU):** a software component that is responsible for storing and processing data obtained from the VSS and SBC. 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. Furthermore, SmartBEAT plans to use data and text mining to build medication knowledge bases, empowering the solution to provide information on therapeutic regimes and to promote medication adherence.

4. **Caregivers portal (CGP):** a web application serving as front-end for the formal and informal caregivers, each with different access permissions. The portal will be tightly integrated with the MIU and will enable caregivers to access the patient's medical data (e.g. vital signs). The portal will also provide them with a personalized news feed, which will highlight important events, such as alerts and changes in patients' vital signs. The news feed will also integrate a semantic search engine to provide recommendations about the last research and scientific initiatives. The portal will allow caregivers to personalize the recommendation by subscribing to semantic topics.
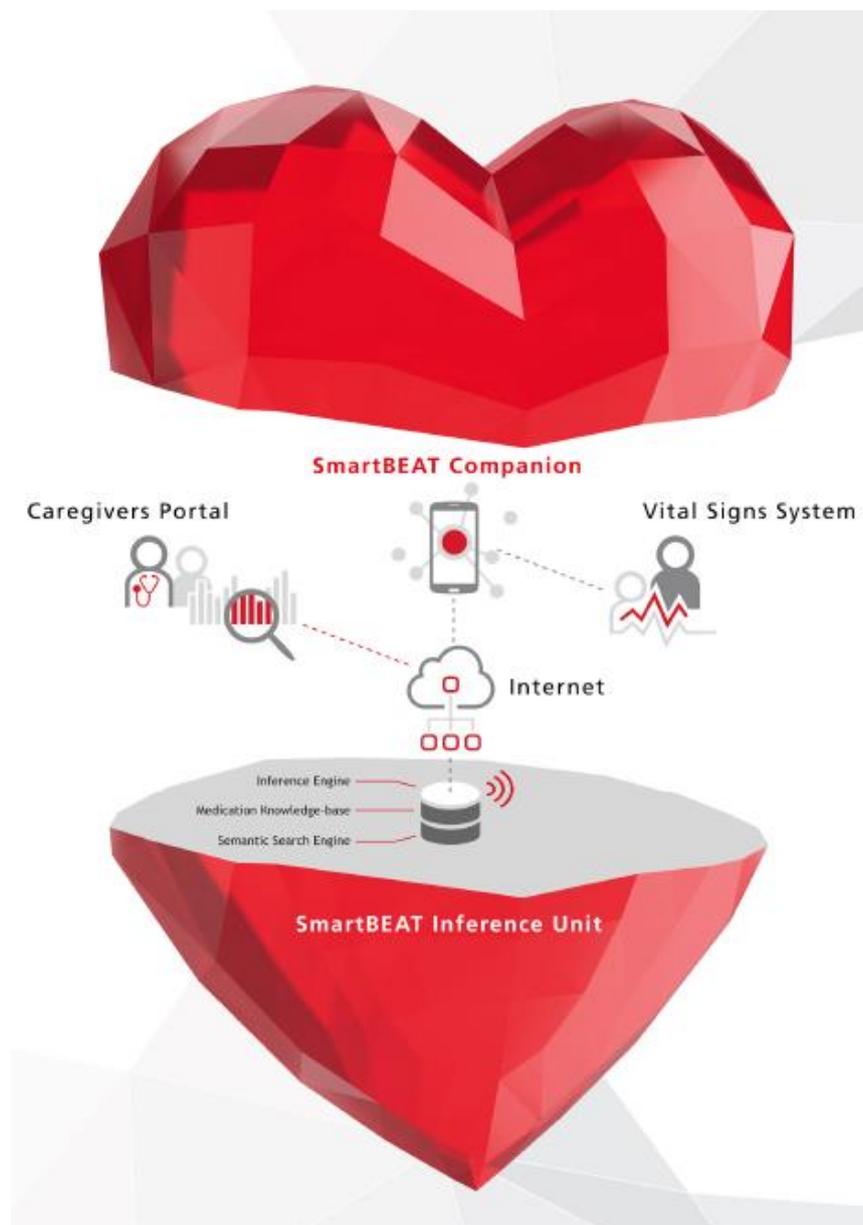
Figure 1 – SmartBEAT technology modules.

1.3.   Overall evaluation strategy

In order to bring the SmartBEAT solution to the market and incorporate it in usual care, different evaluation steps need to be taken, ranging from technical lab validation, over user studies, to end with randomized clinical trials and cost-effectiveness analyses. In this view, an iterative evaluation strategy is proposed.

In the course of the SmartBEAT project, different small-scale evaluation activities will be organized to assess the technical qualities of the SmartBEAT solution on the one hand, and to measure satisfaction and adherence for all different user groups on the other hand. Only if the different users perceive more benefits than effort/burden, it makes sense to set-up large-scale RCT studies to validate its health impact and cost-effectiveness.

1.3.1.   Technical evaluation

Before presenting the SmartBEAT technology to the target population, it should work properly in terms of accuracy and reliability in a controlled environment. The basics for a technical evaluation comprise a verification and validation practice:

- **Verification: Are we building the technology right?**
  The process of evaluating a technology to determine whether the technical solutions of a certain development phase satisfy the conditions imposed at the start of that phase. Through verification, we make sure that the product behaves the way we want, with respect to functionality, reliability and accuracy.
- **Validation: Are we building the right technology?**
  The process of evaluating a technology to determine whether the technical solutions of a certain development phase satisfy earlier specified requirements. Through validation, we check to make sure that the product build is what the customer asked for; validation involves comparison against requirements. In SmartBEAT, this evaluation step focuses on reproducibility testing; validating whether the outcomes from SmartBEAT are in line with the conclusions a team of care professionals draw on the evolution.

1.3.2.   Perceptions

Besides the (more) technical issues discussed above, the SmartBEAT technology and interface will be evaluated from a user point of view. First, interface designers and gerontologists will check the accessibility of the different SmartBEAT interfaces (heuristic evaluation). Second, the technology will be piloted in a lab setting by small groups of real users, both primary users (CHF patients) and secondary users (care professionals).

Based on the outcomes from the heuristic evaluation and the pilot testing, both user and technical requirements will be refined, and the system will be updated accordingly. After this extra step in system development, the final SmartBEAT solution will be evaluated by a larger group of real CHF patients (together with their care network) during a 2-month field trial; in the natural environment and embedded in their daily routines. In addition, the impact of SmartBEAT on informal caregivers will be measured.

1.3.3. Clinical impact

After evaluating the overall perceptions in different user groups, randomized clinical trials need to be organised in follow-up projects to measure the real impacts of using SmartBEAT technology for managing chronic heart failure. With regards to delivering better care, it is important to focus on 3 main objectives simultaneously. This approach is called the "Triple Aim":

- Enhance the patient care experience (including quality, access and reliability)
- Reduce, or at least control, the per capita cost of care
- Improve the health of the defined population
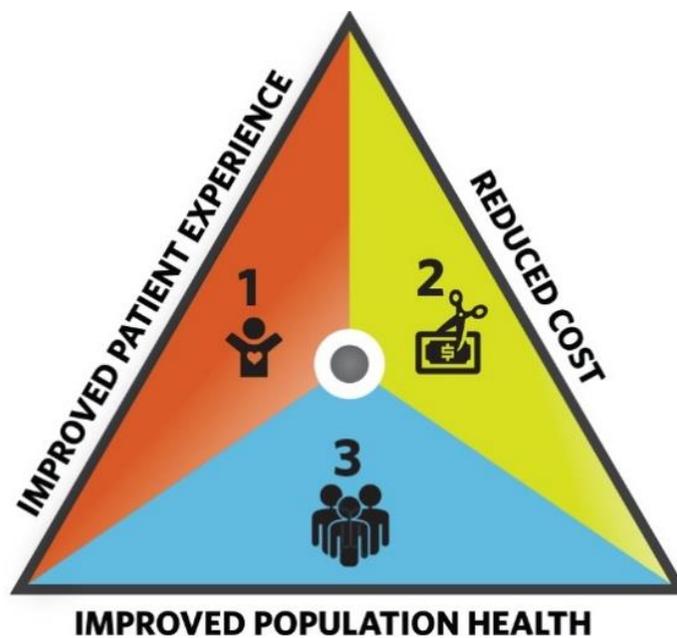
Figure 2 – Healthcare Triple Aim model

In this model, two stages of impact measurement are planned:

- **Medium-scale RCT measuring impact on soft endpoints**
  One RCT study of intermediate dimension and duration with evaluation of the impact on soft endpoints.
- **Large-scale RCT measuring impact on hard endpoints**
  If the medium scale RTC is positive it will be followed by a second one of higher dimension and duration which will evaluate the impact on hard-endpoints:

  - Multicentre trial, possibly international
  - Typically with hundreds of patients (value of sample must be assessed)
  - Unstable patients (in which acute HF (AHF) is likely to occur):
    - o In the post-acute HF vulnerable period
    - o Or, with advanced HF

1.4.   Planning

As described in the sections above, moving from early prototypes to usual care is a long journey. Describing the entire process is going beyond the scope of this single deliverable. The technical evaluation plans, execution and reporting will be part of WP3, and the field trial design plan will be elaborated on in D4.3. The proposed clinical impact studies are seen as the follow-up of the current SmartBEAT project and the plans for those are, therefore, not described in more detail within any project document.

Sequence of testing	Device accuracy Testing Lab validation	Reproducibility testing Device vs doctor measurements	Pilot testing Usability	Field testing Perceived efforts and benefits 2 months	Medium-scale Randomized Clinical Trial Impact on soft endpoints 2 years	Large-scale Randomized Clinical Trial Impact on hard endpoints 4 years
Test Main Endpoint	**Accuracy**	**Reproducibility**	**Usability**	**Perceptions**	**Congestion**	**Hospitalizations**
Device reliability in measuring biological parameters (technical validation)	+					
Reproducibility (device vs doctor)		+				
Patient - usability and correct use			+	+		
Patient - added value and adherence			+	+		
Professional - usability and correct use			+	+		
Professional - added value, adherence, and alignment with standard clinical practice			+	+		
Data consistency (no significant number of outlier measurements and/or false positive alarms)				+	+	+
Clinical relevance (change in medical attitudes due to device data)				+		
Clinical impact – Soft Endpoints (reduction of congestion due to device-oriented strategy)					+	+
Clinical impact – Hard Endpoints (reduction of hospital admissions due to device-oriented strategy)						+

Table 1 – Overall evaluation strategy and planning.

2. Pilot phase: alpha prototype

In WP4, the SmartBEAT alpha prototype will be evaluated from a user perspective. To realize a high level of acceptance – for both senior CHF patients and care professionals – the system needs to be attractive in terms of functionality, design and interaction. Before organizing pilot testing with real CHF patients and care professionals, all the SmartBEAT modules and interfaces will be tested on a technical level and reviewed by multiple gerontologists and interface designers. In this way, technical errors and bugs, major usability issues and design flaws can be taken care of before presenting the technology to pilot test participants.

Goal of the pilot test 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). 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.

Pilot test outcomes report usability issues, other remarks, and suggest changes for the SmartBEAT solution. The prototype will be refined accordingly, in order to end up with a high-quality solution before introducing the SmartBEAT technology for the field trial in the daily lives of real users.
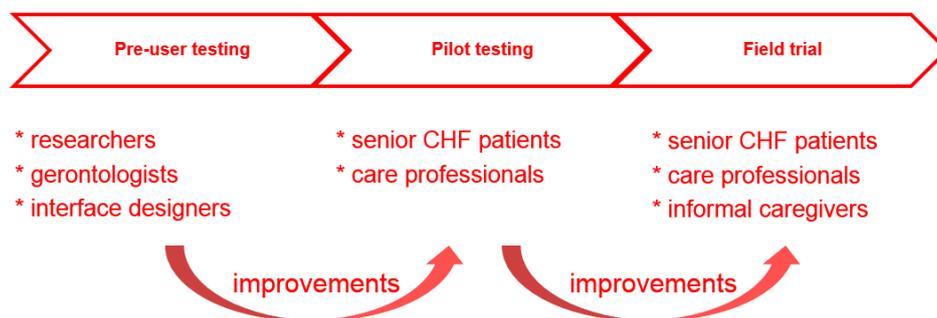
Figure 3 – WP4 evaluation phases.

2.1. Prototype description

In the alpha prototype – to be used in the pilot phase – the major SmartBEAT functionalities are integrated. Patients can do a set of morning measurements (including a daily questionnaire) and will wear a bracelet for continuous measurements. In addition, they will receive different kinds of reminders and coaching messages, register their medication intake and view their measurement history.

Some measurements (e.g. congestion, impedance and heart rate irregularity / arrhytmias) and functionalities will not be part of the alpha prototype, and will be introduced in a later evaluation stage.

- **SmartBEAT Companion app:**
  - Reminder + patient guidance through morning ritual measurements
  - Measurement history data visualization
  - Reminders for medication intake and appointments
  - Medication registration
  - Coaching messages (upon compliance)
- **Morning ritual measurements**
  - Body weight
  - Blood pressure
  - Heart rate in rest
  - SPO2
  - Questionnaire
- **Continuous measurements**
  - Heart rate (value per 15sec interval)
  - Physical activity (loop closed)

- Yunmai – Body scale, model M1501
- MioGlobal – MioFuse
- Jumper Medical Equipment Co. – Oximeter, model JPD500F
- Urion Technology Co. – Sphygmomanometer, model U80E

- Smart phone running the SmartBEAT Companion app (Wiko Pulp / Samsung J3)
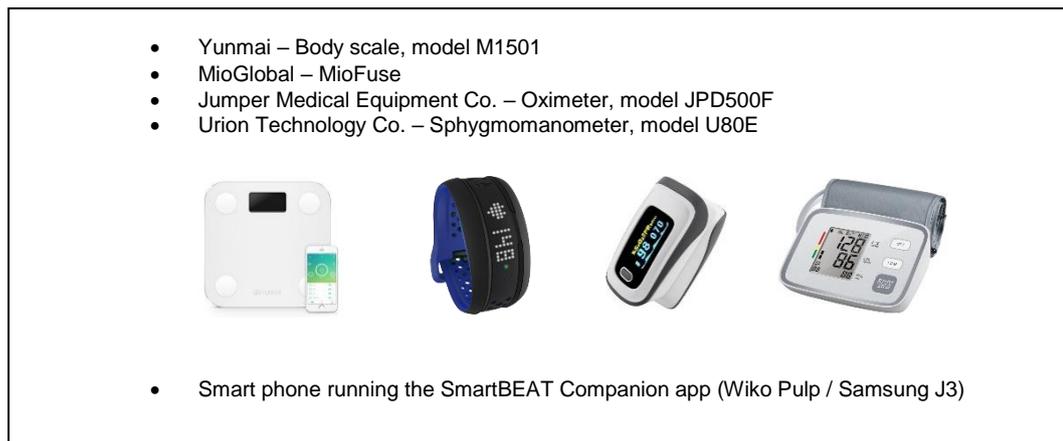
Figure 4 – SmartBEAT patient devices.

The alpha prototype for the care professionals is a Caregivers Portal (web application) to enable them to access the patient's medical data (e.g. vital signs). In the pilot phase, two different CGP's will be used: LifeOnKey CGP in Portugal and Norway and Remedus CGP in the Netherlands and Belgium. Both portals will visualize alerts and changes in patients' vital signs, will enable the doctor to change thresholds and will provide agenda functionality to set a medication regime and to set appointments. The semantic search engine and knowledge base will only be functional for the final prototype to be evaluated in the field trial.

2.2.   Objectives user testing in the pilot phase

Besides, the more technical issues discussed above, the SmartBEAT technology and interfaces will be evaluated from a user point of view. Prior to testing with real users, a heuristic evaluation with gerontologists and interface designers will take place, applying general usability design heuristics and interaction guidelines for common age-related changes (physical limitations, sensory thinning and cognitive decline). Outcomes can serve as input for system improvement, and consequently reduce the number and severity of design errors discovered by users in the next stages of user testing. The plan for this heuristic evaluation is described in chapter 3.

In addition to this expert review, the technology will be evaluated in a lab setting by a small group of real users, both primary users (CHF patients) and secondary users (care professionals), with the eye on further development steps and refinement. During these pilot tests, participants are asked to evaluate perceived usefulness, accessibility and usability of the system, and user-friendliness and clarity of the user manuals. Different evaluation techniques will be applied to extract opinions on the different SmartBEAT components and functionalities, and to discover usability problems and design flaws.

- **Primary users: senior patients with CHF, class II and III**
  Objective of the pilot test 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 4.
- **Secondary users: care professionals**
  Besides primary end-users, the early prototypes need also to be evaluated by secondary users – being care professionals. Besides usability issues, efficiency and alignment with current care systems and care processes are of high importance. The protocol for user tests with care professionals can be found in chapter 5.

Based on the outcomes from the heuristic evaluation and pilot testing with real target subjects, both user and technical requirements will be refined, and the system will be updated accordingly. After this extra step in system development, the final SmartBEAT solution will be evaluated by a large group of real CHF patients and their care network during a 2-month field trial; 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. Different methodologies will be applied for evaluating perceptions from patients, informal caregivers and care professionals. 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.

TECHNICAL TESTING		
Researchers		
Acting as virtual patients + challenging technical performance		
HEURISTIC EVALUATION		
Gerontologists, interface designers		
Usability (Nielsen)		
PILOT TEST EVALUATION		
CHF patients	**Care professionals**	
• Perceived added value • Perceived usability • Perceived design aesthetics • Overall acceptance • Userfriendliness user manuals	• Completeness of the platform • Fit with current care processes • Perceived usability • Perceived design aesthetics • Userfriendliness user manuals	
FIELD TRIAL EVALUATION		
CHF patients	**Informal caregivers**	**Care professionals**
• Perceived health • Perceived quality of life • Feeling of reassurance • Feeling of safety • Feeling of anxiety • Perceived effort • ...	• Impact on informal caregiver	• Impact on quality of care • Impact on efficiency of care

Table 2 – WP4 evaluation phases.

3. Pre-user testing

Before testing with both primary and secondary users, the SmartBEAT prototypes will be evaluated by virtual users on both a technical and usability level. Besides the SmartBEAT Companion app for the senior CHF patients, also the Caregivers Portal interface will be evaluated.

- **Technical evaluation:** A manageable number of systems will be used by virtual patients to investigate technical performance. It has to be ensured that the system works reliably and accurately, and that services operate on clean, correct and useful data and to check for correctness, meaningfulness, and security. In addition, technical testing will evaluate remote services such as updating and trouble shooting.
- **Heuristic evaluation:** The GUI's (graphical user interfaces) of the different SmartBEAT modules will be evaluated by experts, applying a heuristic evaluation approach.

3.1. Technical evaluation

In the pre-user testing phase, people in the different pilot countries will act as patients using the SmartBEAT solution. These people will perform all daily tasks patients would do, in order to check for its proper functioning. This test will challenge the SmartBEAT system, including faulty usage, varying context factors, reliability and remote services.

Daily morning ritual
- Measure body weight
- Measure blood pressure
- Measure heart rate in rest
- Measure SPO2
- Fill out questionnaire
Continuous measurements
- Wear bracelet
- Start measurements
- Check if measurements are displayed on SBC
Receiving reminders and messages
- Check whether reminders come in correctly
- Check whether coaching messages come in correctly
Ad-hoc registrations
- Register 'I am hospitalized'
- Register 'Medication mismatch'
System checks
- Verify battery endurance (sensors and smartphone)
o Perform morning ritual and wear bracelet for full day (measure phone and devices battery before and after)
o To pass the test battery life expectancy of devices should be above 1 day (bracelet 2 days at least and other devices should have 2 weeks)
- Verify Bluetooth functioning
o Configure smartphone to flight mode and perform morning ritual

o SBC should activate Bluetooth when measurement starts (weight, blood pressure, heart rate, activity, SpO2) o Test different ranges for Bluetooth devices to test error messages when devices are not in range - Verify data consumption o Evaluate data consumption for a full day or week o Data consumption should be below 100 MB per month - Verify Wi-Fi functioning o Switch off 3G/4G data and test Wi-Fi connectivity. In case Wi-Fi is available application should also work as expected - Verify 3G/4G data functioning - Switch off 3G/4G data and Wi-Fi to test system for problems. System should be able to work in an offline mode and synchronize data when becomes available again
System remote troubleshooting
- Equipment malfunction and is substituted o Test replacement of phone, configuration of new device with new account. For pilots historic values are not shown to the users but users should be able to perform measurements and to receive data from servers. - Measurements not reported (internet connectivity problems or bug in application) o Use TeamViewer to assist user when internet available (install team viewer in devices and test remote assistance) o Try to solve internet issue remotely by phone (define workflow to assist users remotely and to indicate them how to recover connectivity) o Switch off/on (reset) devices o Substitute equipment (define replacement procedure) - Update app remotely using team viewer or other option when critical bug is found (use google play store for alfa and beta applications - SBC can be updated without any user intervention) o Test application update through google play store or team viewer by sending apk through email account) - App removed from Smartphone – test remote installation and setup using team viewer.

Table 3 – Technical evaluation plan.

3.2. Heuristic evaluation

A heuristic evaluation is a usability inspection method for computer software that helps to identify usability problems in the user interface. This method involves evaluators examining the interface and judging its compliance with recognized usability principles, the so-called "heuristics".

The simplicity of heuristic evaluations is beneficial at the early stages of design. It requires a low number of experts, and can be accomplished in a matter of days. The time required varies with the size and complexity of the system, the purpose of the review, the nature of the usability issues that arise, and the competence of the reviewers.

Besides evaluating the SmartBEAT interfaces on general usability heuristics, the expert reviewers will also verify accessibility of the SmartBEAT Companion app for older adults with minor or major age-related limitations.

Below, the Jakob Nielsen heuristics are presented, probably the most used usability heuristics for user interface design.

Heuristic 1	Visibility of system status
The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.	

Heuristic 2	Match between system and the real world
The system should speak the user's language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.	

Heuristic 3	User control and freedom
Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. Support undo and redo.	

Heuristic 4	Consistency and standards
Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.	

Heuristic 5	Error prevention
Even better than good error messages is a careful design which prevents a problem from occurring in the first place. Either eliminate error-prone conditions or check for them and present users with a confirmation option before they commit to the action.	

Heuristic 6	Recognition rather than recall
Minimize the user's memory load by making objects, actions, and options visible. The user should not have to remember information from one part of the dialogue to another. Instructions for use of the system should be visible or easily retrievable whenever appropriate.	

Heuristic 7	Flexibility and efficiency of use
Accelerators—unseen by the novice user—may often speed up the interaction for the expert user such that the system can cater to both inexperienced and experienced users. Allow users to tailor frequent actions.	
Heuristic 8	Aesthetic and minimalist design
Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.	
Heuristic 9	Help users recognize, diagnose and recover from errors
Error messages should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution.	
Heuristic 10	Help and documentation
Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation. Any such information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.	

Table 4 – Jakob Nielsen's heuristics.

The SmartBEAT system is evaluated with "interface design heuristics" (J. Nielsen) and expertise in "interaction design" in mind. This heuristic analysis will reduce the number and severity of design errors discovered by users in the next stages of user testing. In line with demonstration of new versions of the SmartBEAT system, reports will be written with uncovered usability issues and suggestions for improvement, as input for the developers.

The heuristic evaluation will be executed based on working prototypes of the following modules, in combination with some screenshots for features that are not fully operational yet, and for parts that need to be triggered by certain (external) actions, such as alerts, reminders, etc.

- SmartBEAT Companion app
- Caregivers Portal (Remedus)
- Caregivers Portal (LifeOnKey)

4.   Pilot test protocol CHF patients

Before asking senior CHF patients to implement the SmartBEAT solution in their houses, and to start using it in their daily lives, it is important to guarantee a sufficiently high quality level. In this regard, a round of pilot testing is organized in between the heuristic evaluation study (May-June 2017) and the planned field trials (starting from September 2017).

The pilot tests will be a combination of observations during actual use of the system, individual questionnaires and a group discussion. These tests will give insight in whether the technology fits the needs of the target group, their knowledge, skills and limitations. In addition, it will be tested whether actual use by senior CHF patients has an impact on system reliability. The outcomes of the pilot test will serve as input for a final iteration in technical development before the field trial will start.

In the following sections, the details of the protocol to be used for the pilot test with senior CHF patients are described. In the pilot test with patients the Vital Signs System (VSS), the SmartBEAT Companion (SBC) app and the training material will be evaluated. These tests will be organized in Belgium, Portugal, the Netherlands and Norway.

Figure 5 – SmartBEAT set for CHF patients.

4.1. 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 dyspnea (shortness of breath).
- **NYHA class III** – Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea (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 pilot country – Belgium, Portugal, the Netherlands and Norway – three patients are asked to participate in this activity on a voluntary basis, and can withdraw at any point in time without explanation. For the pilot test, no experience with eHealth/mHealth technology is required.

Below, the recruitment strategies in the different pilot countries are described:

- **Belgium:**
  The cardiology department of Ziekenhuis Oost-Limburg (ZOL) will recruit three senior (65+) CHF patients to participate in the pilot test. 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.
- **Portugal:**
  Three stable CHF patients in NYHA class II or III will be recruited from an outpatient Heart Failure Clinic to participate in this phase of the project.
- **Netherlands:**
  SGE will recruit three stable CHF patients to participate in the pilot test. 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.
- **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, three persons from that group will be recruited: preferably CHF patients as defined above, but most probably hypertension patients.

4.2. Research questions and goals

The SmartBEAT technology provides functionality for senior CHF patients on the one hand, and for care professionals on the other hand. Vitals signs are monitored using different telemonitoring

sensors, and the SmartBEAT Companion app provides patients direct access to their personal data, coaching modules, and interaction with caregivers.

In order to realize a high level of acceptance – especially for an older target population – systems need to be attractive in terms of functionality, design and interaction. To keep the learning curve low, the system should be intuitive. Besides the technology, also user manuals need attention.

The aim of the pilot test is gathering a deeper insight in:

- Influence of human factor on system reliability
- Perceived usability, design aesthetics and comfort of the different SmartBEAT sensors
- Perceived usability and design aesthetics of the SmartBEAT Companion app
- Overall user experience and acceptance
- User-friendliness of the user manuals

4.3.   Methods

The pilot tests 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 pilot test consists of two related parts; the pilot test session and 2 weeks testing at home.

In the pilot test session, senior CHF patients are asked to perform a number of pre-defined tasks using a think-aloud protocol, in order to find out what constitutes an obstacle to effective and efficient interaction with the SmartBEAT Companion app and the vital signs system, and to identify usability problems. After individually using the SmartBEAT technology, patients are asked to fill out a questionnaire to report about their experiences. The pilot test session is concluded with a group discussion, examining topics as overall perceived usefulness, usability, acceptance and suggestions for optimization.

For two weeks, patients will use the SmartBEAT Companion app and vital signs system at home, doing the morning ritual daily. Goal is to evaluate (technical) performance of the system, and to check the impact of human (senior) behaviour on system reliability. After these two weeks, each patient is requested to fill out a short questionnaire to evaluate user experience and effort of the daily process.

4.4.   Tasks

During the pilot test session, the SmartBEAT Companion app is presented. In order to evaluate the intuitiveness of the interface, patients are asked a set of questions. Consequently, patients are requested to perform pre-defined menu and service tasks with the purpose of testing usability, logic, completeness, etc. of the app. For some tasks, the users receive a user manual in order to evaluate the user-friendliness of the training material. Next, patients will use the vital signs system to go through the morning ritual step by step.

Task 1: Usability testing SmartBEAT Companion (SBC) app and VSS
- Intuitiveness of the interface
- Menu and service tasks (without user manual)

- Menu and service tasks (with user manual)
- Morning ritual walkthrough

Task 2: Individual questionnaire
- Usability
- Perceived control

Task 3: Group discussion
- User experience of the SBC
- User experience of the VSS
- Training material

During the two weeks testing period at home, patients are asked to wear the Mio Fuse wristband and do the morning ritual measurements each day. After these two weeks, they are requested to fill out a short, individual questionnaire.

Task 1: SmartBEAT prototype use (2 weeks)
- Measure 4 parameters in daily morning ritual
- Fill out questionnaire (depending on measurements)
- Receiving medication reminders, and registering medication intake
- Receiving coaching messages

Task 2: Individual questionnaire (after 2 weeks)
- Perceived usefulness and usability of the different sensors
- Perceived burden

4.5. Measurements

Different research methods and measurement instruments will be applied in the different parts of the pilot test:

- **Usability:**
  To learn more about the usability of the SmartBEAT system, observations and think aloud protocol are applied while using the system. Patients are asked to comment on specific UI design flaws, but also on their likes or dislikes about certain functionalities of the system. In addition, usability of the overall SmartBEAT system is studied by means of the IBM usability questionnaire (Lewis, 1995 – Appendix 7.3 questions 1-19), and patients are asked to report on any difficulties related to the sensors in the questionnaire (Appendix 7.4) that is administered after the 2-week testing period at home.

- **Perceived control:**
  The level of feeling in control is evaluated based on the observations and think aloud while interacting with the SmartBEAT system. Besides, perceived control will be examined using a perceived control questionnaire (Hinds, 1998 – Appendix 7.4 questions 20-27).

- **Design aesthetics:**
  In the pilot test, feedback on design aesthetics will be gathered during SmartBEAT usage, eliciting perceptions on specific and overall design aspects (e.g., color use, icon design, etc.).

- **Usefulness:**

  Perceived usefulness of the SmartBEAT system is examined during the group discussion. In addition, patients are asked about the perceived usefulness of each sensor in managing the disease – after having used the system for two weeks (Appendix 7.4).

- **User acceptance:**

  Information about user acceptance will be collected during the group discussion, eliciting perceptions on acceptance of eHealth in general and the SmartBEAT system in particular. After the 2 weeks testing period, patients are asked about perceived burden (Appendix 7.4).

4.6. Procedure

The pilot test consists of two parts. First, patients are invited for a test session where patients are requested to use the SmartBEAT VSS and SBC, and evaluate both components and the user manual with a focus on usability. Second, patients use the SmartBEAT technology for a period of two weeks at home, to evaluate (technical) performance of the system on the one hand, and have a first insight in the effort required from patients on the other hand.

Preparation

Two weeks before the pilot test session, patients are informed in detail about the pilot goals and procedures, and are requested to carefully read and sign an informed consent form. In addition, an appointment is set for the week after the pilot test session to provide them with the SmartBEAT system.

Pilot – test session

For the pilot test session, patients are welcomed and reminded about the goals and procedures, and their rights as pilot participants. As qualitative feedback and suggestions for improvement are most important, a rather open protocol with a variety of qualitative measurement tools will be used to evaluate the SmartBEAT Companion app, telemonitoring sensors and user manuals.

1. **Cognitive walkthroughs with think-aloud protocol**

   Patients are presented the SmartBEAT Companion app and are asked questions to investigate whether the app is intuitive and whether the menu structure is logically built. Extra questions can give an insight in the clarity and comprehensiveness of the app, and the visualisation of measurement data. Consequently, patients receive a user manual and are invited to complete a set of pre-defined tasks, in order to evaluate the user-friendliness of the user manual.

   Furthermore, patients are asked to go through the daily morning ritual procedure, using the SmartBEAT Companion app and the different telemonitoring sensors, in order to evaluate the different SmartBEAT sensors and the support from the SmartBEAT Companion app. In addition, it is showed how they have to register medication intake.

   To gather as much feedback as possible, each individual user is observed by an experimenter; the idea is that the user explains his handlings to the experimenter (think-aloud). Additionally, the experimenter poses questions and notes down relevant observations and quotes.

2. **Individual questionnaires**

   Besides being observed, the patients are asked to fill out a small questionnaire concerning perceived usefulness, usability, perceived control, etc.

3. **Group discussion**

   In addition to the individual questionnaires, all the patients are invited to take part in a group discussion, concerning perceived usefulness, usability, completeness, additional services and features, etc.

To conclude the session, patients are debriefed and receive an information sheet about the goals and following steps within the SmartBEAT project.

The patient test session will take approximately 2 hours in total.

Pilot – 2 weeks testing

In the week after the pilot test session, the patients are visited at home to provide them with the SmartBEAT vital signs system (VSS) and the smart phone running the SmartBEAT Companion app. Together with the experimenter, sensors are unpacked and installed, and patients are explained how and when to use them.

1. **SmartBEAT prototype use**

   Each day, the patient receives a reminder to take his measurements. Upon compliance, patients receive coaching messages. In addition, they are requested to register their medication intake. It is explained to them that the SmartBEAT system is still in a testing phase, and that technical reliability might hamper. Therefore, they better contact their doctor when they do not feel well.

2. **Individual questionnaires**

   Each patient is requested to fill out a short questionnaire about their experiences using the SmartBEAT system, and the effort (burden) it takes.

4.7.   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 pilot test 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 pilot 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
- Image / video recordings

These country-specific pilot 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-pilot comparison.

4.8. Location and equipment

Pilot test sessions with senior CHF patients need to take place in a relaxing environment, where they can feel at ease – preferably a home-like environment. It is advisable to have three different rooms available to split up the group and have individual tests with each patient. Afterwards all patients will come together for the joint group discussion.

- **Belgium:**

  In Belgium the pilot test session will take place in dedicated meeting rooms of the Mobile Health Unit (MHU) – a research organisation related to Hasselt University and two hospitals in Limburg province. It occupies a section of the ZOL hospital in Genk where three separate rooms will be made available for the pilot test.

- **Portugal:**

  In Portugal, the pilot test session will take place in the Heart Failure Outpatient Clinic in Centro Hospitalar São João.

- **Netherlands:**

  In the Netherlands, the pilot test session with CHF patients will take place in the Smartest Home of the Netherlands, a test and demonstration facility of Smart Homes. This house permanently serves as a tool for testing new products and services. As the interior of the house resembles that of a normal home, people feel more at ease, and can better imagine how it would be like to use the SmartBEAT solution at home.

- **Norway:**

  In Norway, the pilot session will be organized in the Seniornett premises in Oslo. Different meeting rooms and offices will be prepared.

For the pilot test with patients, we need – in each country – three smart phones running the SmartBEAT Companion app, and three vital signs systems. In addition, a digital camera will be used to take high-resolution images of the user test setting and to capture unexpected system behavior. A voice (audio) recorder can be used to record the group discussion.

4.9. 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 pilot test with the Belgian patients, there will be three experimenters: one project manager from Remedus, one researcher from Smart Homes and one researcher from the Mobile Health Unit. The responsible cardiologist will be Prof. Dr. Pieter Vandervoort.
- **Portugal:**
  The pilot test 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 pilot test 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 pilot test 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.

4.10. Documents and materials

The following materials are prepared for the pilot test session with senior CHF patients.

- **Project information flyer_patients**   *** appendix 7.1**
- **Informed consent form_patients**   *** appendix 7.2**

- Scenario with the procedure for the test session
- Cognitive walkthrough instructions and task description
- Group discussion instructions
- User manual for the SmartBEAT Companion app
- Quick reference card for morning ritual
- **Individual questionnaire (pilot test session)**   *** appendix 7.3**
- **Individual questionnaire (2 weeks testing)**   *** appendix 7.4**

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

5.   Pilot test protocol care professionals

In the following sections, details of the protocol used for the pilot test with care professionals are described. The pilot test consists of a group session where the SmartBEAT system – and in particular the Caregivers Portal – is demonstrated, and where care professionals are asked to perform some tasks individually and give feedback about their experience. In later stages, more feedback can be gathered back-to-back with demonstrations of new versions.

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

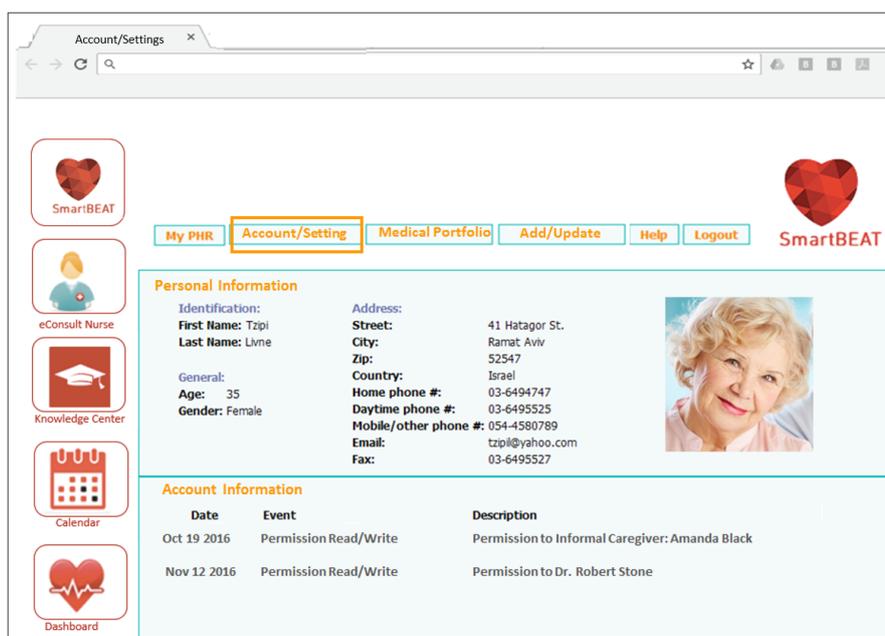**Figure 6 –** SmartBEAT CGP Remedus.

Figure 7 – SmartBEAT CGP LifeOnKey.

5.1.   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, physical therapists, case managers and social workers. In the three pilot countries, different types of care professionals will be involved. Below, the recruitment strategies are described:

- **Portugal:**
  There will be no formal recruitment strategy. The medical team involved in the project will recruit other peers based on referrals within their work environment.
- **Belgium:**
  Remedus has already identified three heart failure nurses to participate in the pilot test. 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 pilot test. 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.

5.2.   Research questions and goals

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 care 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. Besides the technology itself, also user manuals will be evaluated in terms of user-friendliness.

The aim of the pilot test is gathering a deeper insight in:

- Completeness of the platform
- Fit with current care processes
- Perceived usability of the platform
- Perceived design aesthetics of the platform
- User-friendliness of the user manuals

5.3. Methods

Different caregivers have different roles, different expertise, and different tasks. Each caregiver has specific access rights and specific functionalities – and all of these might differ from country to country. Therefore, we organize the care professional evaluation activities based on a role-based approach rather than profession-based. We do not use a very strict protocol for the tests, as we are convinced that qualitative feedback is most useful in this stage.

The pilot tests with care professionals are dedicated to the evaluation of the SmartBEAT caregivers portal. First, a demo is organized to show the portal and its functionalities. Second, professionals are asked to evaluate the current version of the system; they are requested to perform a number of pre-defined tasks, check whether the menu is logical and complete, and report about their findings in quantitative and qualitative ways. Besides self-administered questionnaires and open feedback forms, experimenters do observations and ask questions in a semi-structured way. If necessary, this approach can be repeated with updated versions later.

5.4. Tasks

During the test, professionals perform pre-defined menu and service tasks with the eye on testing usability, logic, completeness, etc. In order to gather as much feedback as possible, professionals receive feedback collection forms with different open questions. In addition, experimenters pose questions and note down relevant observations and quotes.

Task 1: Usability testing of the CGP
- Intuitiveness of the interface
- Menu and service tasks (without user manual)
- Menu and service tasks (with user manual)

Task 2: Individual questionnaire
- Usability
- Perceived control

Task 3: Individual feedback collection
- Perceived usefulness vs. perceived effort
- Completeness and alignment with existing infrastructure and current care processes

Task 4: Group discussion
- User experience of the CGP
- Training material

5.5.   Measurements

Different research methods and measurement instruments will be applied in the different parts of the care professionals pilot test. For evaluating usability, perceived control and design aesthetics of the SmartBEAT Caregivers Portal an identical questionnaire will be used as the one patients use for evaluating the SmartBEAT Companion app (described in section 4.5).

In addition, alignment with daily work and care processes will be evaluated, using the following measurements.

- **Completeness of the SmartBEAT Caregivers Portal:**
  During task completion, caregivers are observed to check the system for incompleteness. In addition, they are asked to report about missing functionalities and features in the portal and interesting additions for the future (Appendix 7.8). Afterwards, the raised issues will be discussed in more detail during the group discussion.
- **Fit with existing care processes:**
  During task completion, experimenters observe the care professionals in order to recognize inconsistencies with their expectations and familiar procedures. Next, care professionals are asked to report about misfits or suggestions to restructure the menu, or other changes to better fit current care processes (Appendix 7.8). All the issues that pop up, will be further discussed in the group discussion.

5.6.   Procedure

The pilot test with care professionals starts with a plenary demo of the portal. Step by step, one experimenter presents the different functionalities of the Caregivers Portal using a beamer. Next, professionals are invited to complete pre-defined tasks – first without extra documentation to evaluate intuitiveness, later with a user manual, to evaluate clarity and comprehensiveness of the training material. Next, they are asked to report their thoughts on feedback collection forms while interacting with the system. Afterwards, they are asked to check the menu and screens for logic and completeness. To conclude, they are invited to fill-out a questionnaire about usability.

Pilot – test session
For the pilot test session, care professionals are welcomed and explained about the procedure of the study; emphasized that sessions aim at testing the technology and not users' performances. They are requested to sign an informed consent. The informed consent states what is being studied, ensures anonymous analysis, announces audio and image recordings and explains clearly that they can withdraw their consent and cooperation at any given point in time during or after the study. In the pilot test session, a rather open protocol will be applied focussing on detecting design flaws, and formulating system improvements. In the pilot test session, mostly qualitative measurement tools will be used to evaluate the SmartBEAT Caregivers Portal and user manuals.

1. **Demo**

   The Caregivers Portal is demonstrated to a small groups of care professionals, highlighting the functionalities and features by going through the menu, and showing different use cases and options.

2. **Cognitive walkthroughs with think-aloud protocol**

   Care professionals are asked to perform a set of pre-defined menu and service tasks with the purpose of testing usability, logic, completeness, etc.

   In order to gather as much feedback as possible, each individual care professional is observed by an experimenter; during task completion, care professionals explain their handlings to the experimenters (think-aloud). Additionally, experimenters pose questions and note down relevant observations and quotes.

3. **Individual questionnaires**

   Besides being observed, the care professionals are asked to fill out a small questionnaire concerning perceived usefulness, usability, perceived control, etc.

4. **Individual feedback collection form**

   In order to gather as much feedback as possible, the care professionals receive a feedback collection form with several open questions.

5. **Group discussion**

   To conclude the pilot test session, the proposed SmartBEAT solution will be discussed in group with the eye on perceived usefulness, completeness of the platform and fit with current care processes and infrastructure and care processes.

At the end of the session, care professionals are debriefed and receive information about the goals and next steps within the SmartBEAT project.

The care professional test session will take about 2-4 hours in total.

5.7.   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 pilot test 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 pilot report, in order to make proper analysis and interpretation. These data include:

- Notes from experimenters with observations and quotes from care professionals
- Data from the self-administered questionnaires
- Data from the self-administered feedback forms
- Image / video recordings

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

5.8.   Location and equipment

The pilot test sessions with care professionals need to take place in their professional habitat, where they are familiar and in their "care professional" mode.

- **Portugal:**
  The pilot test with cardiologists in Portugal will take place in the Heart Failure Outpatient Clinic in Centro Hospitalar São João.
- **Belgium:**
  The pilot test sessions with heart failure nurses in Belgium will take place in a large meeting room of the cardiology department of the ZOL hospital. Since all three heart failure nurses work in the hospital, it will be easy for them to attend the session.
- **Netherlands:**
  In the Netherlands the pilot test sessions will take place at the central location of SGE, in the meeting room of the building Strijp-Z. The nurse practitioners are familiar with the central location of their organization.

In these three locations, a computer needs to be provided for each care professional, running the Caregivers Portal. In the CGP, representative data needs to be entered in advance, simulating a real patient.

In addition, a beamer needs to be installed for the demo and a digital camera will be used to take high-resolution images of the user test setting and of users performing in the test. The camera can also be used to capture unexpected system behavior. A voice (audio) recorder can be used to record the group discussion.

5.9.   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 pilot test with cardiologists in Portugal will be conducted by three cardiologists that are part of the project team (Prof. Silva Cardoso, Dr. Carla Sousa and Dr. Sérgio Leite).
- **Belgium:**
  For the pilot test with Belgian care professionals (three heart failure nurses), there will be three experimenters: one project manager from Remedus, one researcher from Smart Homes and one researcher from the Mobile Health Unit.
- **Netherlands:**
  For the pilot test 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.

5.10. Documents and materials

The following materials are prepared for the pilot test session with care professionals.

- **Project information flyer_care professional**   *** appendix 7.5**
- **Informed consent form_care professional**   *** appendix 7.6**

- Scenario with the procedure for the test session
- Cognitive walkthrough instructions and task description
- Group discussion instructions
- User manual for the SmartBEAT Caregivers portal
- **Individual questionnaire**   *** appendix 7.7**
- **Individual feedback collection form**   *** appendix 7.8**

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

7.   Appendices

7.1.   Appendix 1 – Project information flyer_patients

SmartBEAT project

"Information sheet"

Title of the project: SmartBEAT
Funding: European Commission & [National Funding Agency]
Coördinator: Fraunhofer, Portugal
Duration: 2015-2018

Longevity is one of the biggest achievements of modern societies; Europeans are living longer than ever before and this pattern is expected to continue due to unprecedented medical advances and improved standards of living.The number of healthy life years, however, appears to remain unchanged. In this way, an increasing number of elderly people spend 20-25% of their lives in poor health, suffering from one or more chronic diseases, such as Chronic Heart Failure (CHF). Combined with low birth rates, this will bring significant changes to the structure of European societies, resulting in a very high pressure on the healthcare system.

In light of these challenges, the SmartBEAT project – Smart system for Heart Failure management – is funded in Call 7 of the AAL Programme. The main goal of the project is to support senior CHF patients, their family, relatives and friends, cardiologists and general healthcare professionals accessing innovative ICT solutions that promote an easier, wider and sustainable access to healthcare. SmartBEAT offers an integrated solution to leverage patient self-care through autonomous condition monitoring and real-time feedback to their carers. Using SmartBEAT, it is possible to improve health outcomes and enhance the patients' quality of life.

Although technology has great potential, both patients and care professionals tend to have numerous reasons to be reluctant to innovative care solutions. In order to tackle this reluctance and realize user acceptance, both user groups have been involved in service and system definition, so to align the SmartBEAT technology with daily life of senior CHF patients and with current care processes and infrastructure.

PILOT TEST WITH CHF PATIENTS

As described above, senior CHF patients have been involved in the early phases of the project to align the SmartBEAT solution with their needs, wishes, skills and limitations. Before introducing the technology in their daily lives and evaluating it in a large-scale field trial, a pilot test is planned with a low number of users in a controlled environment.

In the pilot test, patients are closely involved in order to map perceived usefulness, overall acceptance, and user-friendliness of both the system and the user manuals. Goal is to find out what constitutes obstacles to effective and efficient interaction with the SmartBEAT Companion app and the vital signs system, and to identify any usability problems. Outcomes of the pilot test will serve as input for a final iteration in technical development before the field trial will start.

7.2.   Appendix 2 – Informed consent form_patients

SmartBEAT project

"Informed consent"

Dear,

You are kindly invited to participate in the **PILOT TEST** described below. This activity is part of the European research project SmartBEAT. Before you agree on participating, it is important to read carefully this consent form and understand the procedure. If you have any questions or remarks, do not hesitate to let us know.

1. PROJECT AIM
The aim of the SmartBEAT project is to develop and evaluate a smart system for the management of CHF in older adults: an integrated solution to leverage patient self-care through autonomous condition monitoring and real-time feedback to their caregivers.

2. OBJECTIVE OF THE PILOT TEST
The objective of the Pilot test is to gain insight in whether the technology fits the needs of the target group, their knowledge, skills and limitations. In addition, it will be tested whether actual use by senior CHF patients has an impact on system reliability. Based on the outcomes, the SmartBEAT technology will be refined for the field trial.

3. PROCEDURES
In the pilot test session, senior CHF patients are asked to perform a number of pre-defined tasks using a think aloud protocol, to evaluate the usability of the SmartBEAT Companion and the vital signs system. After individually using the technology, patients are asked to fill out a questionnaire and take part in a group discussion.

Consequently, patients are requested to use the SmartBEAT Companion app and vital signs system at home for two weeks, doing health measurements each morning. Goal is to evaluate (technical) performance of the system, and the impact of human (senior) behaviour on system reliability. After these two weeks, each patient is requested to fill out a short questionnaire to evaluate user experience and effort of the daily process.

4. VOLUNTARY PARTICIPATION
The Pilot test targets senior CHF patients (65+). No previous experience with eHealth technology is required. You are asked to participate in this activity on a voluntary basis. You can withdraw at any point in time without explanation.

5. RISKS
No risks to expect.

6. ADVANTAGES
Your personal experience and opinion are valuable input. This information is the basis for further R&D activities in the field of eHealth and CHF management.

7. ANONIMITY AND PRIVACY
Directly identifying information is removed from the data and replaced by a participant code, in order 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.

Information from the Pilot test will be mainly used for internal reports. Some outcomes might be used for SmartBEAT dissemination and Journal or Conference publications.

8. CONTACT DETAILS

For more information about your rights as participant, for further questions or in case you are unsatisfied about the way the Pilot test is executed, you are free to contact the following researchers:

- **Wil Rijnen – Smart Homes – w.rijnen@smart-homes.nl**
  Responsible for general user research procedures.
- **[Name – organisation – email@email.com]**
  Responsible for execution of the Pilot test in [country].

9. CONFIRMATION

If you are still interested to participate in the SmartBEAT Pilot test, please check the boxes below, and confirm your participation with your full name, date and signature on the bottom of the page.

<u>Check the boxes</u>

1   I have carefully read this document. I had the opportunity to ask for clarification, and I confirm that I understand all information.   ☐

2   Based on the information, I agree to participate voluntarily in the Pilot test.   ☐

3   I agree on making audio recordings.   ☐

4   I agree on making image recordings.   ☐

5   My data can be used for the above described communication and research purposes.   ☐

Participant code: SMB-PILOT-NL-PAT-1

_____   _____   _____
Name Participant   Date   Signature

_____   _____   _____
Name Researcher   Date   Signature

7.3.   Appendix 3 – Patient questionnaire (pilot test session)

SmartBEAT project

"Pilot test session - questionnaire"

Participant code:

Thanks for your participation in the SmartBEAT Pilot test for CHF patients. We would like to learn about your experiences using the SmartBEAT Companion app. Based on your experience and answers, the technology can be optimized. Important to keep in mind is that we are investigating the functionality and quality of the system, not your performance.

Please indicate for each item how you have experienced the smart phone application (screen lay-outs, buttons, control, etc.), using the following scale.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Usability

1. Overall, I am satisfied with how easy it is to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

2. It was simple to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

3. I could effectively complete the tasks and scenarios using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

6. I felt comfortable using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

7. It was easy to learn to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

8. I believe I could become productive quickly using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

9. The system gave error messages that clearly told me how to fix problems.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

11. The information (such as online help, on-screen messages and documentation) provided with this system was clear.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

12. It was easy to find the information I needed.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

13. The information provided by the system was easy to understand.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

14. The information was effective in helping me complete the tasks and scenarios.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

15. The organisation of information on the system screens was clear.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

16. The interface of this system was pleasant.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

17. I liked using the interface of this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

18. This system has all the functions and capabilities I expect it to have.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

19. Overall, I am satisfied with this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Perceived Control

20. I felt that I was in control.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

21. I was able to work according to my own approach.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

22. When I planned on doing something, I was able to make it work.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

23. I have a pretty good idea of how the system works.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

24. I felt responsible for performing the tasks well.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

25. I felt discouraged while performing the tasks.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

26. I felt good about my performance on this task.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

27. At some points, I felt like giving up.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

User experience

28. I would like to use this system again.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

29. It was nice to discover the system functionalities.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

30. I think other CHF patients would like this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Additional remarks

If you want, you can add additional remarks here:

_____

_____

_____

_____

_____

7.4. Appendix 4 – Patient questionnaire (2 weeks testing)

SmartBEAT project

"Pilot 2 weeks - questionnaire"

Participant code:

Thanks for your participation in the SmartBEAT Pilot test for CHF patients. We would like to learn about your experiences using the SmartBEAT Companion app and the different health monitoring devices. Based on your experience and answers, the technology can be optimized. Important to keep in mind is that we are investigating the functionality and quality of the system, not your performance.

Please indicate for each item how you have experienced the technology), using the following scale.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

SmartBEAT Companion app on the smart phone

1. I believe this system has added value in managing CHF, for me as a patient.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

2. I believe this system has added value in managing CHF, for my care professional.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

3. It was simple to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Did you experience any technical problems or difficulties in using this system, please explain.

_____

_____

_____

_____

_____

If you want, you can add additional remarks here:

_____

_____

_____

_____

_____

SmartBEAT weight scale

4. I believe this system has added value in managing CHF, for me as a patient.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

5. I believe this system has added value in managing CHF, for my care professional.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

6. It was simple to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Did you experience any technical problems or difficulties in using this system, please explain.

_____

_____

_____

_____

_____

If you want, you can add additional remarks here:

_____

_____

_____

_____

_____

SmartBEAT bloodpressure cuff

7. I believe this system has added value in managing CHF, for me as a patient.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

8. I believe this system has added value in managing CHF, for my care professional.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

9. It was simple to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Did you experience any technical problems or difficulties in using this system, please explain.

_____

_____

_____

_____

_____

If you want, you can add additional remarks here:

_____

_____

_____

_____

_____

SmartBEAT activity and heart beat monitor (bracelet)

10. I believe this system has added value in managing CHF, for me as a patient.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

11. I believe this system has added value in managing CHF, for my care professional.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

12. It was simple to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Did you experience any technical problems or difficulties in using this system, please explain.

_____

_____

_____

_____

_____

If you want, you can add additional remarks here:

_____

_____

_____

_____

_____

SmartBEAT oximeter

13. I believe this system has added value in managing CHF, for me as a patient.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

14. I believe this system has added value in managing CHF, for my care professional.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

15. It was simple to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Did you experience any technical problems or difficulties in using this system, please explain.

_____

_____

_____

_____

_____

If you want, you can add additional remarks here:

_____

_____

_____

_____

_____

Daily morning ritual

For the last two weeks, you were requested to do a number of measurements each morning, and we are eager to know how you have experienced this daily morning ritual. Please answer the following questions. All your answers and comments are valuable for us in order to improve the SmartBEAT system.

16. How long did it take – on average – to take all the measurements?

- ☐ Less than 05 minutes
- ☐ Between 05 and 15 minutes
- ☐ Between 15 and 30 minutes
- ☐ More than 30 minutes
- ☐ I do not know

17. Are you able to do your measurements today in a shorter time period after using the system for two weeks?

- ☐ Yes, I need much less time
- ☐ Yes, I need a little less time
- ☐ No, I need the same amount of time
- ☐ No, I need more time
- ☐ I do not know

18. Did you take all the measurements each day?

- ☐ Yes
- ☐ No, I skipped some days, but on the days I measured, I used all devices.
- ☐ No, I measured each day, but did not use all devices.
- ☐ No, I measured according to my own ideas

19. If you did not take all measurements each day, can you please explain why you have decided not to do so?

_____

_____

_____

_____

_____

20. It takes some time and effort to do all measurements each day. Are you willing to do the complete morning ritual each day so that the care professional can follow-up your health status in detail and intervene when necessary?

☐ Yes, absolutely
☐ Probably
☐ Maybe
☐ No

21. Are you willing to do the complete morning ritual each morning for 1 month, so that the care professional is able to analyse your personal data and adapt the monitoring regime according to your personal needs?

☐ Yes, absolutely
☐ Probably
☐ Maybe
☐ No

Bracelet

22. How did you experience wearing the bracelet 24/7?

_____

_____

_____

_____

_____

23. Can you list reasons and/or activities where you have taken off the bracelet?

_____

_____

_____

_____

_____

Medication reminders and intake registration

24. How did you experience receiving medication reminders on the smartphone? Are these helpful for you or do you perceive these as annoying and/or superfluous?

_____

_____

_____

_____

_____

25. Can you list technical issues or difficulties you have experienced in registering your medication intake in the smartphone?

_____

_____

_____

_____

_____

7.5.   Appendix 5 – Project information flyer_care professional

SmartBEAT project

"Information sheet"

Title of the project: SmartBEAT
Funding: European Commission & [National Funding Agency]
Coördinator: Fraunhofer, Portugal
Duration: 2015-2018

Longevity is one of the biggest achievements of modern societies; Europeans are living longer than ever before and this pattern is expected to continue due to unprecedented medical advances and improved standards of living.The number of healthy life years, however, appears to remain unchanged. In this way, an increasing number of elderly people spend 20-25% of their lives in poor health, suffering from one or more chronic diseases, such as Chronic Heart Failure (CHF). Combined with low birth rates, this will bring significant changes to the structure of European societies, resulting in a very high pressure on the healthcare system.

In light of these challenges, the SmartBEAT project – Smart system for Heart Failure management – is funded in Call 7 of the AAL Programme. Main goal of the project is to support senior CHF patients, their family, relatives and friends, cardiologists and general healthcare professionals accessing innovative ICT solutions that promote an easier, wider and sustainable access to healthcare. SmartBEAT offers an integrated solution to leverage patient self-care through autonomous condition monitoring and real-time feedback to their carers. Using SmartBEAT, it is possible to improve health outcomes and enhance the patients' quality of life.

Although technology has great potential, both patients and care professionals tend to have numerous reasons to be reluctant to innovative care solutions. In order to tackle this reluctance and realize user acceptance, both user groups have been involved in service and system definition, so to align the SmartBEAT technology with daily life and work.

PILOT TEST WITH CARE PROFESSIONALS
As described above, care professionals have been involved in the early phases of the project to align the SmartBEAT solution with current care processes and the existing infrastructure. Before introducing the technology in their daily work and evaluating it in a large-scale field trial, a pilot test is planned with a low number of users in a controlled environment.

In the pilot test, care professionals are closely involved to map perceived usefulness, overall acceptance, and user-friendliness of both the SmartBEAT Caregivers Portal and user manual. In addition, the pilot test focusses on completeness of the technology and its fit in CHF management. Goal is to refine the system before starting a large-scale field trial. The system should be as reliable and user-friendly as possible in order to avoid mistakes and time loss.

7.6.   Appendix 6 – Informed consent form_care professional

SmartBEAT project

"Informed consent"

Dear,

You are kindly invited to participate in the **PILOT TEST** described below. This activity is part of the European research project SmartBEAT. Before you agree on participating, it is important to read carefully this consent form and understand the procedure. If you have any questions or remarks, do not hesitate to let us know.

1. PROJECT AIM
The aim of the SmartBEAT project is to develop and evaluate a smart system for the management of CHF in older adults: an integrated solution to leverage patient self-care through autonomous condition monitoring and real-time feedback to their caregivers.

2. OBJECTIVE OF THE PILOT TEST
The objective of the Pilot test is to gain insight in whether the technology fits the needs of the target group, including alignment with current care processes and infrastructure. Based on the outcomes, the SmartBEAT technology will be refined for the field trial.

3. PROCEDURES
The Pilot test with care professionals is dedicated to the evaluation of the SmartBEAT Caregivers Portal. First, a demo is organised to show the portal and its functionalities. Second, care professionals are asked to evaluate the current status of the system; they perform a number of pre-defined tasks, check whether the menu is logically built and complete, and report about their findings in a self-administered questionnaire and open feedback collection form.

4. VOLUNTARY PARTICIPATION
The Pilot test in [country] targets [cardiologists, CHF nurses, general practitioners], preferably with experience in telemonitoring for CHF. You are asked to participate in this activity on a voluntary basis. You can withdraw at any point in time without explanation.

5. RISKS
No risks to expect.

6. ADVANTAGES
Your personal experience and opinion are valuable input. This information is the basis for further R&D activities in the field of eHealth and CHF management.

7. ANONIMITY AND PRIVACY
Directly identifying information is removed from the data and replaced by a participant code, in order 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.

The information from the Pilot test will be mainly used for internal reports. Outcomes might be used for SmartBEAT dissemination and Journal or Conference publications.

8. CONTACT DETAILS

For more information about your rights as participant, for further questions or in case you are unsatisfied about the way the Pilot test is executed, you are free to contact the following researchers:

- **Wil Rijnen – Smart Homes – w.rijnen@smart-homes.nl**
  Responsible for general user research procedures.
- **[Name – organisation – email@email.com]**
  Responsible for execution of the Pilot test in [country].

9. CONFIRMATION

If you are still interested to participate in the SmartBEAT care professional Pilot test, please check the boxes below, and confirm your participation with your full name, date and signature on the bottom of the page.

<u>Check the boxes</u>

1 **I have carefully read this document. I had the opportunity to ask for clarification, and I confirm that I understand all information.** ☐

2 **Based on the information, I agree to participate voluntarily in the care professional Pilot test.** ☐

3 **I agree on making audio recordings.** ☐

4 **I agree on making image recordings.** ☐

5 **My data can be used for the above described communication and research purposes.** ☐

Participant code: SMB-PILOT-NL-PROF-1

_____   _____   _____
Name Participant   Date   Signature

_____   _____   _____
Name Researcher   Date   Signature

7.7. Appendix 7 – Care professional questionnaire

SmartBEAT project

"Pilot test care professionals - questionnaire"

Participant code:

Thanks for your participation in the SmartBEAT Pilot test for care professionals. We would like to learn about your experiences using the SmartBEAT Caregivers Portal. Based on your experience and answers, the technology can be optimized. Important to keep in mind is that we are investigating the functionality and quality of the system, not your performance.

Please indicate for each item how you have experienced the SmartBEAT Caregivers Portal (screen lay-outs, buttons, control, etc.), using the following scale.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Usability

1. Overall, I am satisfied with how easy it is to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

2. It was simple to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

3. I could effectively complete the tasks and scenarios using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

4. I was able to complete the tasks and scenarios quickly using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

5. I was able to efficiently complete the tasks and scenarios using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

6. I felt comfortable using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

7. It was easy to learn to use this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

8. I believe I could become productive quickly using this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

9. The system gave error messages that clearly told me how to fix problems.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

10. Whenever I made a mistake using the system, I could recover easily and quickly.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

11. The information (such as online help, on-screen messages and documentation) provided with this system was clear.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

12. It was easy to find the information I needed.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

13. The information provided by the system was easy to understand.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

14. The information was effective in helping me complete the tasks and scenarios.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

15. The organisation of information on the system screens was clear.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

16. The interface of this system was pleasant.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

17. I liked using the interface of this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

18. This system has all the functions and capabilities I expect it to have.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

19. Overall, I am satisfied with this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

Perceived Control

20. I felt that I was in control.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

21. I was able to work according to my own approach.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

22. When I planned on doing something, I was able to make it work.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

23. I have a pretty good idea of how the system works.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

24. I felt responsible for performing the tasks well.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

25. I felt discouraged while performing the tasks.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

26. I felt good about my performance on this task.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

27. At some points, I felt like giving up.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

User experience

28. I would like to use this system again.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

29. It was nice to discover the system functionalities.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

30. I think my colleagues would like this system.

Strongly agree	1	2	3	4	5	6	7	Strongly disagree

7.8. Appendix 8 – Care professional feedback collection form

SmartBEAT project

"Pilot test care professionals - feedback collection form"

Participant code:

With the eye on improvement of the SmartBEAT Caregivers Portal, we are interested to learn about your experiences and your concrete suggestions for change. Please explain the strengths and weaknesses of the portal, and describe in detail how the system can be improved to support you best in your profession.

Question 1: How do you experience the menu structure of the Caregivers Portal? Are the menu items clear, and do they reflect content correctly? Is it clear where to find which information?

_____
_____
_____
_____
_____
_____
_____

Question 2: Do you think menu items are in a logical order, or would you prefer to re-structure the menu?

_____
_____
_____

_____
_____
_____
_____

Question 3: Do you have the impression that it takes many steps to reach a certain screen, or does the system give you quick access to what you need?

_____
_____
_____
_____
_____
_____
_____

Question 4: Is it clear what information you are able and/or allowed to alter?

_____
_____
_____
_____
_____
_____
_____

Question 5: Do you think the system is well aligned with existing care processes?

_____
_____
_____
_____
_____

_____

_____

Question 6: Can you describe in what sense this system can have an added value in your profession?

_____

_____

_____

_____

_____

_____

_____

Question 7: Can you imagine items or functionalities that you would like to be added to the system?

_____

_____

_____

_____

_____

_____

_____

Question 8: Please report 3 positive aspects of the system.

_____

_____

_____

_____

_____

_____
_____

Question 9: Please report 3 negative aspects of the system.

_____
_____
_____
_____
_____
_____
_____

Question 10: Do you have any other remarks or additional comments that you would like to share with the R&D team?

_____
_____
_____
_____
_____
_____
_____