ROBOTS IN ASSISTED
LIVING ENVIRONMENTS

UNOBTRUSIVE, EFFICIENT, RELIABLE AND MODULAR SOLUTIONS FOR INDEPENDENT AGEING

Research Innovation Action

Project Number: 643892 Start Date of Project: 01/04/2015 Duration: 36 months

DELIVERABLE 6.2

Piloting Plan II

Dissemination Level	**Public**
Due Date of Deliverable	March 2016, Project Month 12
Actual Submission Date	4 April 2016
Work Package	WP6, *Piloting and Evaluation*
Task	T6.1, *Piloting plan development*
Lead Beneficiary	FSL
Contributing beneficiaries	NCSR-D, S&C, ROBOTNIK, AVN
Type	Report
Status	Submitted
Version	Final

Project funded by the European Union's Horizon 2020 Research and Innovation Actions

Abstract

This report plans the *intermediate phase of pilots* that will test the first prototype of the RADIO system, including the first prototype of the RADIO GUI, the RADIO Main Controller, and the robotic platform. These trials will inform technical packages about the stability and usability of the system, as well as about the procedures for making parallel human observations for estimating the accuracy of the data.

History and Contributors

Ver	Date	Description	Contributors
00	22/02/2016	First draft, working on document structure and incorporating the information regarding the study participants.	NCSR-D, FSL
01	17/03/2016	Additions to Section 3 regarding technical characteristics of the pilot.	NCSR-D, S&C, ROBOTNIK, AVN
02	24/03/2016	Pre-final version prepared	FSL
03	29/03/2016	Internal peer review.	TWG
04	04/04/2016	Addresses peer review comments.	FSL
Fin	04/04/2016	Final preparations and submission.	NCSR-D

Executive Summary

This report plans the *intermediate phase of pilots* that will test the first prototype of RADIO system (i.e. the first prototype of RADIO GUI and robotic platform) in order to inform about the usability of the system and the procedures for making parallel human observations for estimating the accuracy of the data. More specifically, this report details the profile and number of pilot participants and how long they will work with the consortium and the criteria to be used for subject selection. It also includes a scenario description. The main purpose of scenarios is to provide a communication tool between the different groups of experts involved in the project. The scenario encapsulates both knowledge about how the system can be useful, and what is technically feasible. A scenario is a description of a user's interaction with a system. Finally, it describes the study design, the data that will be collected and the policies for data retention and analysis. This report also appends the consent forms that will be used for the study subjects and the safety certification of the used hardware.

Abbreviations and Acronyms

ADL	Activities of Daily Living
ASQ	After-Scenario Questionnaire
IADL	Instrumental Activities of Daily Living
interRAI	International collaborative to improve the quality of life of vulnerable persons through a seamless comprehensive assessment system. Cf. http://www.interrai.org
interRAI HC	The *interRAI* Home Care Assessment System
interRAI LTCF	The *interRAI* Long-Term Care Facilities Assessment System
MMSE	Mini Mental State Examination
PIADS	Psychosocial Impact of Assistive Devices Scale
SUS	System Usability Scale

CONTENTS

Contents iv
List of Figures v
List of Tables vi
1 Introduction 1
1.1 Purpose and Scope 1
1.2 Approach 1
1.3 Relation to other Work Packages and Deliverables 3
2 Intermediate phase: Materials and Methods 4
2.1 Participants 4
2.2 Study Design 4
2.2.1 Description of experimental setting 4
2.2.2 Training Description 5
2.2.3 Scenario Description 5
2.2.4 Study procedures and Outcomes 6
2.3 Variables and Instruments 6
2.3.1 Procedures 6
2.3.2 Questionnaires 6
2.3.3 Statistical analysis 7
2.4 Data Retention 8
3 Technical Requirements and Planning 9
3.1 Graphical User Interface and Clinical Staff Update 9
3.2 Communication between user's GUI and robot 9
3.3 Recognition methods and components 9
3.4 Robot Design and Robot Behaviour 9
3.5 Communication between Smart Home Sensor and Main controller 10
3.6 Technical Requirements at Piloting Site 11
References 12
Appendix I 13
Appendix II 9
Appendix III 15
Appendix IV 17

LIST OF FIGURES

Figure 1: Dependencies between this deliverable and other deliverables. 3
Figure 2. RADIO GUI with 'Guide me' functionality 10
Figure 3: Indicative locations of bed (1), table (2), robot (3) and motion sensor(4). 10
Figure 4: 2D Map of Intermediate Phase pilot premises at FSL. 11

LIST OF TABLES

Table 1. Technical requirements at piloting site 11

1 INTRODUCTION

1.1 Purpose and Scope

RADIO presents a domestic assistant and home automation profile to the end-user, which most importantly acts as an unobtrusive health monitoring system.

RADIO's main objective is an unobtrusive monitoring system whose equipment is an obvious and accepted part of the user's daily life, by adopting a smart home/assistant robot approach, where the sensing equipment actively strives to be obvious and closely located to the user; that is, we propose that robot companions and assistants are used to collect the data needed for medical monitoring.

RADIO system will provide a pool of ICT based in-home services that will be offered to elderly users that live at home to improve time spent autonomously at home. Although the RADIO system is primarily presenting a domestic assistant and home automation profile, it is also acting as an unobtrusive health monitoring system and as an instrument for medical evaluation. It will ensure the timely availability of the patients' clinical and behavioral data to allow timely prognosis and clinical actions. Through its direct involvement in end-users' daily activities, RADIO observes *activities of daily life* and *mood*. These observations are used to establish patterns and identify deviations. Moreover, RADIO empowers new care service provisioning models based on the remote supervision of the elderly/patients from the medical experts and/or health professionals or caregivers. It deals with the extraction/derivation of reinforced medical knowledge associated with symptoms, good practices, treatments and personalized patterns of treatment for elderly users.

Objectives of the study:

- Measure validity of the Radio system
- Evaluate functional activities and mood
- Improving Quality of Life
- Measure Usability

This report plans the *intermediate phase of pilots* that will test the first prototype of RADIO system (i.e. the first prototype of RADIO GUI and robotic platform) in order to inform about the usability of the system and the procedures for making parallel human observations for estimating the accuracy of the data. More specifically, this report details the profile and number of pilot participants and how long they will work with the consortium and the criteria to be used for subject selection. This report also includes a scenario description. The main purpose of scenarios is to provide a communication tool between the different groups of experts involved in the project. The scenario encapsulates both knowledge about how the system can be useful, and what is technically feasible. A scenario is a description of a user's interaction with a system. It then describes the study design, the data that will be collected and the policies for data retention and analysis. This report also appends the consent forms that will be used for the study subjects and the safety certification of the used hardware.

1.2 Approach

This is a non-experimental clinical study. The target population is elderly people who need assistance in order to maintain their independence and quality of life.

The study will be distributed in three phases:

1. Formative phase; first pilot at FSL
2. Intermediate phase; second pilot of RADIO components at FSL
3. Summative phase; final RADIO pilots Phases and other elements of the organization of the work leading to this document.

Formative phase: The first pilot will be carried out at FSL premises with elderly end-users. The objectives of this pilot are (a) to provide data for a purely formative evaluation of the usability of existing user interfaces for controlling home automation and (b) to refine the piloting plan itself into its second version.
Intermediate phase: The second round of pilot, also at FSL premises, will be realized with the first versions of user interfaces, devices, and the robotic platform delivered on M12 and M15. The objectives of this pilot are (a) to provide data for the formative evaluation of early RADIO components for usability and fitness for purpose; and (b) to refine the piloting plan itself into its third version.
Summative phase: This final phase includes two sets of pilots, one at FHAG premises and one at the private homes of FZ clients who have volunteered to participate, implementing the third version of the piloting plan. The objectives of these pilots are (a) to validate the prototype of the overall RADIO ecosystem; and (b) to provide data for the final, summative user evaluation report and medical evaluation report.
This deliverable plans the intermediate piloting phase.
The steps leading up to carrying out the intermediate pilot are as follows:

ROBOTNIK	Create a simulated environment based on floor plans sent by FSL. The simulated environment will be used to test the standard ROS navigation packages on our specific environment.	Feb/Mar 2016
NCSR-D	Collect datasets for testing recognition methods for chair transfer and 4m timed walk	
TWG	Collect datasets for testing recognition methods for bed transfer and medicine intake	
NCSR-D, TWG, AVN	Finalize the recognition method software that will be used at the second FSL trials	By end-Mar 2016
NCSR-D	Delivery of D5.4, first RADIO GUI prototype	Mar 2016
FSL	Decide on the specific two rooms that will be used and the position reserved for the gateway and the main controller. All locations must have wifi connectivity and both rooms must be reachable by the gateway over zWave. The position reserved for the PC must also have fixed network socket to a network reachable by the Wifi network. FSL will test the connectivity (Wifi and zWave) and report on any problems.	By end-Mar 2016
ROBOTNIK	Finalize the prototype design.	Mid-May 2016
NCSR-D	Develop a first version of the main controller that collects data and prepares the daily report.	
ROBOTNIK	Delivered one unit to NCSR-D and one unit to TWG	Mid-June 2016
NCSR-D, ROBOTNIK	Set up and testing at FSL premises	Late June to early July 2016

NCSR-D and ROBOTNIK will support the pilot with personnel on site (before and during the first days) and on the phone/email (throughout the whole pilot).

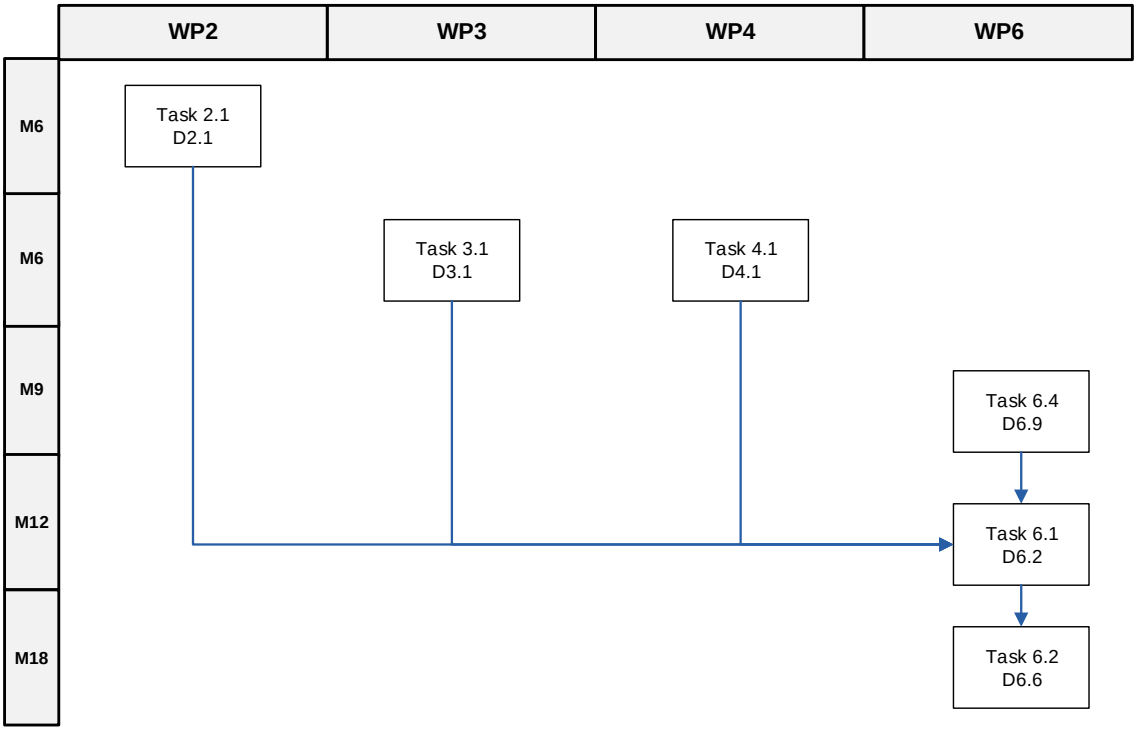

Figure 1: Dependencies between this deliverable and other deliverables.

1.3 Relation to other Work Packages and Deliverables

This deliverable is prepared within Task 6.1 *Piloting plan development* and it describes the pilot planning of the intermediate phase of the pilots. The selection criteria of the participants were firstly described in *D2.1 Early detection methods & relevant system requirements I*. Moreover, this deliverable takes into account the results of the formative phase pilot trials as reported in *D6.9 User evaluation report I.*

The ADL items recognition that is going to be tested during the immediate phase pilot was decided based on *D3.1 Conceptual architecture for sensing methods and sensor data sharing I*, *D4.1 Architecture for extending smart homes with robotic platforms I* and the outcomes of the 1st plenary meeting concerning the scenario of the intermediate phase trials.

This report plans the trials that will be carried out at FSL premises in the context of Task 6.2 *Controlled pilot trials* (M16-M18) to produce D6.6 *Controlled pilot trials report II*.

These dependencies and interactions are also graphically depicted in Figure 1.

2 INTERMEDIATE PHASE: MATERIALS AND METHODS

This phase is dedicated to evaluation of the usability and fitness of purpose of first RADIO prototype. It will last for three months (M16-M18). These subjects will be selected from among a population resident at FSL. All subjects will be tested on ADL, IADL, mood-behaviour and cognitive aspects through interRAI LTCF specific sections and on usability through System Usability Scale (SUS), Psychosocial Impact of Assistive Devices Scale (PIADS) and After-Scenario Questionnaire (ASQ). Data will be collected for each subject for 1 week.

2.1 Participants

The user-groups comprise 36 elderly participants.

Inclusion criteria

- Older than 64 years old
- Ability to walk without human assistance indoors
- Need supervision in almost two IADLs
- Willing to participate in the study and wanting to co-operate in all its parts, accepting the performance regulations and procedures provided by the researchers

Exclusion criteria

- Moderate/severe mental disease, such as dementia, according to clinical criteria -DSM-IV-TR and MMSE score ≤18 or neuropsychiatric disorders.
- Moderate/Severe disability ADL< 4
- Acute medical conditions
- Unable to fully understand the potential risks and benefits of the study and give informed consent. Subjects who are unable or unwilling to cooperate with study procedures.
- Blind
- Deaf
- Languages problems

Moreover FSL will involve in the study 24 caregivers as volunteers.

2.2 Study Design

2.2.1 Description of experimental setting

The test will take place inside the Neurorehabilitation C Department of Fondazione S. Lucia premises.

The Neurorehabilitation C Award provides rehabilitation for people with neurologic deficits resulting from cerebrovascular (stroke) disease, central nervous system diseases (Parkinson's disease, multiple sclerosis and myelopathy). Our goal is to help patients become as independent as possible so they can return to daily life. To ensure each of our patients is receiving the best care possible, our team of experts, also called an interdisciplinary team, leads patients through their individualized rehabilitation programs. Any adult patient who has suffered an accident, illness or injury accompanied by a significant functional limitation that prevents a return to home and community is a candidate for inpatient rehabilitation services at FSL. Patients have functional disabilities in one or more of the following areas:

- activities of daily living
- cognition
- communication
- pain management
- bowel or bladder control
- swallowing
- mobility

Each individual's treatment team is made up of physical, occupational, and speech therapists, rehabilitation nurses and a case manager, as well as neuropsychology services as appropriate. They work together with the patient and their family/caregiver to meet the unique physical, cognitive, social and emotional needs of the patient. Patients are expected to participate in at least 3 hours of therapy per day, 5 days per week. On average, our patients participate in 3 to 4 hours of therapy each day Monday through Friday and a lesser amount of therapy on Saturday and Sunday.

The experimental study will be tested with volunteer subjects and participants will be recruited among those admitted to Neurological C Department.

The RADIO system will be integrated in the routine activity of each patient.

A typical day in inpatient rehabilitation:

MEAL TIMETABLE:

- breakfast h:7.30
- lunch h:12.30
- dinner h:18.30

DIURNAL WORKING ACTIVITY

- Each patient has one session of physical therapy to the morning (40 min) and in the afternoon (40 min)
- Some patients have one session of logopedics rehabilitation.
- Some patients have one session of cognitive rehabilitation.
- Some patients have one session of phoniatrics rehabilitation during the lunch.
- Some patients carry out one session of respiratory rehabilitation outside the unit.
- Some patients carry out one session of hydro-kinesis-therapy (therapy in swimming pool situated 50 meters from the unit)

2.2.2 Training Description

Before the intermediate phase starts, the RADIO system will be installed at the participants' room. Once the system is properly deployed and tested, the participant will be trained in using the system.

All the users of the system will receive clear protocols and users' manual written in their own language. A telephone number for doubts and technical incidences will be given to the participants, who will be able to contact the research team by using this phone number, at any time during the fieldwork. All the technical partners involved in the RADIO project will provide timely support when necessary at the local places of the pilots.

If training is not successful in the first time, a second visit will be scheduled to re-train the users needing it. As stated in the exclusion criteria, those participants unable to operate the system will be excluded of the study.

2.2.3 Scenario Description

"A user is using the phone app to ask the robot to be guided to the gym (or some other room). The robot moves to the gym followed by the user, waits for the user to come out of the gym, and follows him to the room. The user keeps the smartphone at hand or in a pocket during this, allowing us to test user tracking via the mobile device's Bluetooth signal. Walking speed measurement can be done by the robot during walking to and from the gym. Once back at the room the robot monitors the user for: medication uptake, bed transfer when waking up and getting off the bed (time needed from lying in bed to standing

up and walking 4m). Similarly, for time needed from sitting in a chair to standing up and walking 4m. Besides the robot, a motion sensor will be place in such a way that motion while lying in bed can be detected in order to notify the main controller to wake up the robot (if the robot is turned off to re-change)"

2.2.4 Study procedures and Outcomes

Objectives:

- Usability of the RADIO system
- Validity of the RADIO system

For the pilot study, all subjects will give written informed consent for participation in the study. In this phase we will enroll patients that satisfy inclusion/exclusion criteria as defined in the D2.1 and agree to participate in the study.

Before starting any experimental test each user will be assessed trough multidimensional evaluation by InterRAI (see D2.1). After the baseline assessment, the scheduled program will consist of an experimental protocol lasting for 1 week.

We plan to evaluate 36 subjects among a population resident at Neurorehabilitation C Department of FSL, from July until the end of September. Moreover, we plan to evaluate 24 caregivers about usability of the RADIO system.

2.3 Variables and Instruments

This section lists the instruments and procedures that will be used to measure the outcomes that are the focus of this phase of the study.

Usability Measures (user and caregiver)

- SUS questionnaire
- ASQ questionnaire
- PIADS questionnaire
- Custom-made questionnaire for caregiver

Measures of validity of the RADIO system

- Custom-made questionnaire to collect data on the recorded ADL (see below) from users, caregivers and nurses staff

2.3.1 Procedures

Right after that patient finished his/hers scenario each user will be evaluated with usability questionnaires:

- System Usability Scale (SUS)
- Psychological Impact of Assistive Device Scale (PIADS)
- After Scenario Questionnaire
- Moreover, at the end of the experimental protocol caregiver will be interviewed on usability through a dedicated questionnaire (SUS) and a custom-made questionnaire.

2.3.2 Questionnaires

The **System Usability Scale (SUS)** is a simple, ten-item scale giving a global view of subjective assessments of usability. It consists of a 10 item questionnaire with five response options for

respondents: from Strongly agree to Strongly disagree. Originally created by John Brooke in 1986 [1], it allows to evaluate a wide variety of products and services, including hardware, software, mobile devices, websites and applications.

The System Usability Scale actually covers a variety of aspects of system usability, such as the need for support, training, and complexity, and thus has a high level of face validity for measuring usability of a system. SUS scores have a range of 0 to 100.

The **Psychological Impact of Assistive Device Scale (PIADS)** [2] is a scale designed to measure the impact of assistive product of the quality of the subject's life. This questionnaire is composed by self-administered 26-item and it investigates three psycho-social aspects:

- Competence: Measures feelings of competence and usefulness.
- Adaptability: Signifies a willingness to try new things.
- Self-esteem: Indicates feelings of emotional wellbeing and happiness

The competence subscale is composed of 12 items related to perceived functional capability, independence, and performance (examples: adequacy, efficiency, and skillfulness). The adaptability subscale is composed of 6 items that reflect inclination or motivation to participate socially and take risks (examples: ability to participate, willingness to take chances, and ability to take advantage of opportunities). The self-esteem subscale is composed of 8 items reflecting self-confidence, self-esteem, and emotional wellbeing (examples: sense of control, happiness, and self-confidence).

PIADS can be used to assess the impact of any assistive device (AD), prosthesis or medical procedure, and can be used with people of all ages and abilities. The test is self-administered in pencil-and-paper form. Each item in scored through a 7-points scale. Scores can range from –3 (max. negative impact) to +3 (max. positive impact).

The **After Scenario Questionnaire** [3] is to be given to a study subject after he/she has completed a normal condition scenario. The user is to circle their answers using the provided 7 point scale (the lower the selected score, the higher the subject's usability satisfaction with their system). After the user has completed the ASQ, the ASQ score can be calculated by taking the average (arithmetic mean) of the 3 questions:

- Overall, I am satisfied with the ease of completing this task.
- Overall, I am satisfied with the amount of time it took to complete this task.
- Overall, I am satisfied with the support information (on-line help, messages, documentation) when completing this task

2.3.3 Statistical analysis

Below we provide an introduction of the statistical methodology to evaluate RADIO objectives

2.3.3.1 Measures of usability

As already introduced in D2.1 usability analysis will be performed by a descriptive study of the results of the various questionnaires used for this purpose. Where appropriate, the results will be compared with previously established limits in the operating instructions of these questionnaires.

About PIADS, positive scores above the midpoint (0) will be considered as a perceived positive change in competence, adaptability and self-esteem as a result of using the device.

About SUS a score above 68 (the average score among 500 studies[1]) will be considered as a general positive perceived usability of the tool. Moreover, a specific evaluation of each scenario will be obtained

[1] Please cf. http://www.measuringu.com/sus.php

with the ASQ questionnaire and scores of this scale will be correlated with the general score obtained at SUS.

2.3.3.2 Measuring the accuracy of activities of daily life (ADL) recognition

In order to evaluate RADIO performance we will produce a confusion matrix summarizing how many times different activities (ADL / mood) were misclassified by the system compared with data collected by caregiver/FSL dedicated professional. From this matrix a set of common metrics such precision, recall, accuracy and the F1 score (harmonic mean of precision and recall) will be also calculated for each activity. For a complete description see D2.1.

2.4 Data Retention

All reports and communications relating to study subjects will identify the subject only by his/her initials and case number. The investigator will complete subject identification on a confidential site log, which will be used for the purposes of traceability and follow-up. This will be treated with strict adherence to professional standards of confidentiality, and will be filed under adequate security and restricted accessibility.

The Principal Investigator, or his designee, in accordance with institutional policy, will obtain an Informed Consent that is reviewed and accepted by the Ethics Committee. A written consent form bearing the full name, date and signature of the patient and the local investigator will be obtained from each patient. The signed Informed Consent constitutes a confidential document and therefore should be archived in the study binder. A copy of the consent should be given to the patient.

3 TECHNICAL REQUIREMENTS AND PLANNING

3.1 Graphical User Interface and Clinical Staff Update

As described earlier in the pilot's scenario, the end users use the *RADIO Graphical User Interface* (GUI) to ask to be guided to the gym (or some other room) by the robot. This GUI is developed within Task 5.2 and it follows the requirements provided by the Formative Phase usability study (*D6.9 User evaluation report I).* Although in its final form RADIO GUI offers access to various functionalities related to the robot, the smart home devices, and social networking, the current prototype focuses on supporting the Intermediate Phase pilots and only offers the 'Guide me' functionality. The user will ask to be guided to the gym, to his room or to another room (see characteristic screenshot, Figure 2). Three possible notifications can be received: a) the robot is coming, b) the robot is busy, c) already in this room – please select another room.

Clinical staff will receive daily an email with a report on recognized interRAI items, as decided during the first plenary meeting. This will be implemented by NCSR-D. During the *Summative Phase pilots* all clinical information will be found in the Hospital GUI.

3.2 Communication between user's GUI and robot

The communication between the robot and the RADIO GUI is mediated by the main controller's REST API and the robot's REST API (REST API over ROS functionality).

3.3 Recognition methods and components

The following ADLs are recorded: walking speed, medication intake, bed transfer when waking up and getting off the bed and time needed to stand up from sitting in a chair.

The relevant recognition methods and components are developed to record the required ADLs:

- Image processing for detecting movement from a lying position to standing up
    - This component measures the time it takes to transfer from lying position to standing up
- Image processing for detecting that a medicine cap is used or otherwise moved
    - This component verifies if a paper cap is picked, not required to verify intake.
- Walking speed detection from 3D or laser scanner
    - This component measures the times it takes to perform x-measured meters.

The first two ADLs are recognized by image processing. The images are captured by the camera located on the robot (Figure 3). While monitoring for these ADLs, the robot is stationed at a known location, where both the bed and a table (where the medication cap is placed) are visible. NCSR in cooperation with TWG will provide the framework for capturing a sequence of image in real time. AVN will provide low power algorithms and -in coordination with TWG- will port them on the Robot. NCSR will also process the output of the ADL detection algorithms so that the events can be recorded.

Trigger for starting the image capture and detect procedure will be provided by a motion sensor placed close to the bed, ideally at a location that captures both the person sleeping and the surface of the table.

3.4 Robot Design and Robot Behaviour

The robotic platform used for the test will be the first design of the RADIO robot (Deliverable 4.6).

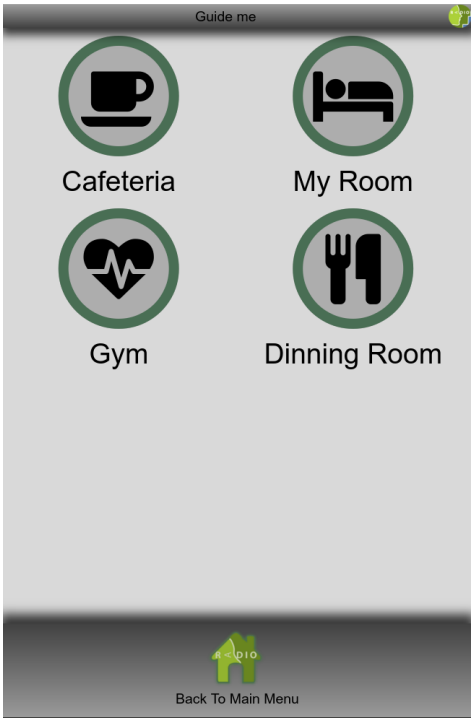

Figure 2. RADIO GUI with 'Guide me' functionality

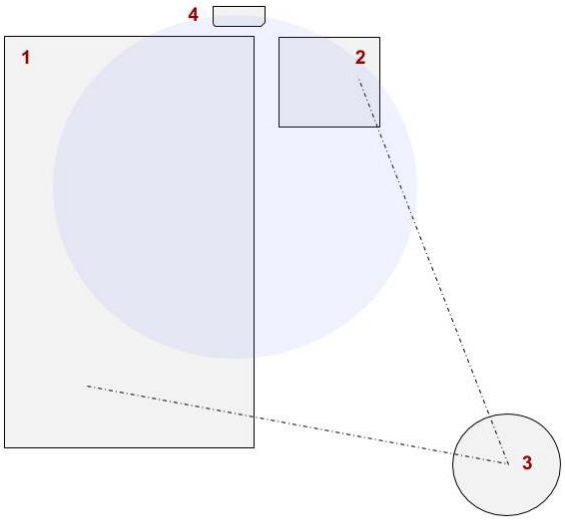

Figure 3: Indicative locations of bed (1), table (2), robot (3) and motion sensor(4).

The robot will be composed by:

- The Turtlebot 2 mobile platform

- A Hokuyo URG04 2D laser

- An Asus Xtion Pro Live RGBD camera

- Two embedded controllers: a NUC pc and a FPGA

- WiFi and Bluetooth Low Energy connectivity

NCSR and ROBOTNIK will cooperate on navigation and other needed robot behaviours. These methods are first to be tested on a simulated environment for testing navigation. ROBOTNIK will prepare simulated environment based on maps provided by FSL (Figure 4).

The robot will be able to create a 2D map of the environment by using its 2D laser and mapping algorithms. This map will be saved and shared with all the robot platforms used for the trials.

Once the map is created and shared, the robots will be able to localize by using the AMCL (Adaptive Monte Carlo Localization) algorithm implemented and available in ROS. For the navigation, the robots will use the ROS navigation stack, which provides several tools to navigate through a map, looking for the optimal path and avoiding obstacles and collisions.

3.5 Communication between Smart Home Sensor and Main controller

Besides the robot, a motion sensor will be placed in such a way that motion while lying in bed can be detected in order to notify the main controller to wake up the robot (if the robot is turned off to re-charge).

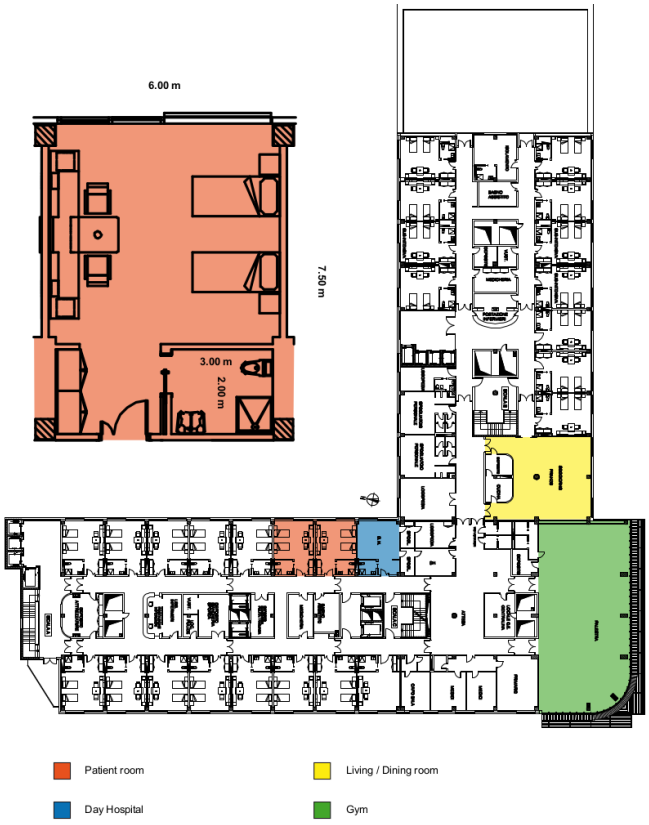

Figure 4: 2D Map of Intermediate Phase pilot premises at FSL.

3.6 Technical Requirements at Piloting Site

Table 1. Technical requirements at piloting site

Requirement	Comments
RADIO Robots x 2	The rooms must have power outlets for robot charging, ideally as shown in Figure 3
Motion Sensors x 2	It takes 2-3 weeks to receive SH sensors since ordering date.
Networked fixed PC	The position of this PC must be in a place where: a) The zWave sensor (SH motion sensor) can be received (both rooms must be reachable by the gateway over zWave). b) There is fixed network socket to a network reachable by the Wi-Fi network. [FSL will test the connectivity (Wi-Fi and zWave) and report on any problems.]
Wi-Fi connectivity	All locations must Wi-Fi have connectivity. [FSL will test the connectivity and report on any problems.]
Mobile devices x 2	Android devices for the end-user RADIO GUI

REFERENCES

1. Brooke J (1996) SUS: A ‘quick and dirty’ usability scale. In: Jordan PW, Thomas B, Weerdmeester BA, McClelland IL (eds) *Usability evaluation in industry*. Taylor & Francis, London, pp 189–194
2. Jutai J, Day H. Psychosocial Impact of Assistive Devices Scale (PIADS). *Technology and Disability* 2004; 14:107-111
3. Lewis JR. An after-scenario questionnaire for usability studies: Psychometric Evaluation over three trials. SIGCHI Bull., Vol. 23, No. 4. (1991)

APPENDIX I

This appendix presents the English-language *Participant Information and Consent Form* that informs participants about the project and explains the tests and treatments involved.

Participant Information and Consent Form (PICF)

Project: Robots in assisted living environments:

Unobtrusive, efficient, reliable and modular solutions for independent ageing (RADIO)

H2020-PHC-2014-single-stage 643892

Headed with Institution's name or on Institution's Letterhead

Participant Information and Consent Form

[Insert Institution's name]

Full Project Title: Robots in assisted living environments: Unobtrusive, efficient, reliable and modular solutions for independent ageing (RADIO)

Principal Researcher: ***[Insert researcher name]***

1. Introduction

You are invited to take part in the RADIO project. This innovation project will develop and evaluate a platform, which enables to improve time to be spent autonomously at home by users. It will ensure the timely availability of the user's clinical and behavioural data to allow timely prognosis and clinical actions from the medical expert and/or health professional or care-givers.

This Participant Information and Consent Form informs you about the project. It explains the tests and treatments involved. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this project is **voluntary**. If you don't wish to take part, you don't have to. **You will receive the best possible care whether you take part or not**.

If you decide you want to take part in the project, you will be asked to sign the consent section. By signing it you are telling us that you:

- ☐ understand what you have read;
- ☐ consent to take part in the project;
- ☐ consent to have the tests and treatments that are described;
- ☐ consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

The project will develop and evaluate a platform, which enables to improve time to be spent autonomously at home by users. Technological partners will provide their innovative solutions to be integrated in the new platform and evaluated by several healthcare organizations across Europe.

The goal of RADIO is to develop methods for detecting the activities of daily life (ADL) and mood conditions that are pertinent for detecting early symptoms of cognitive impairment; frailty, and social exclusion, and to compare them against what can be achieved by more obtrusive setups (that affect quality of life of primary end users) or by placing the burden of constant monitoring on their care givers.

This project will enable to evaluate how well the RADIO-provided information can serve the purpose of detecting early symptoms of cognitive impairment, so that admissions and days spent in care institutions for precautionary reasons can be drastically reduced.

The effectiveness of the solutions will be evaluated by over 100 elderly users/patients across different countries, cultures, age groups and risk factors.

The RADIO system will consist in a domestic assistant robot that robot exhibits a behaviour akin to that of a pet.

This research is being conducted by the RADIO Consortium and sponsored by the European Commission under the H2020 program - H2020-PHC-2014-single-stage 643892.

3. What does participation in this research involve?

An experimental multicentre and multinational clinical trial will be performed. The study will be conducted on 164 elderly participants living at home or in residential care. The participants will be located in 3 pilot sites.

To be included in the trial each user must meet a set of conditions called, inclusion criteria. Participants who satisfy inclusion criteria will be assigned to one of the following groups:

1. 30 participants will be enrolled in the Formative phase group; the pilot at Fondazione Santa Lucia – FSL (Italy)

2. 36 participants will be enrolled in the Intermediate phase group; the pilot of RADIO components at FSL: 36 users

3. 82 participants will be enrolled in the Summative phase group; 24 users at Granoillers-FHAG (Spain), 24 users and 24 caregivers at Frontida - FZ (Grece)

1. Formative phase. The first pilot will be carried out at FSL premises. This phase will be used to collect data useful for the following phase. Each patient will be required to attend one session. Each session will be 30 minutes duration.

2. Intermediate phase. The second round of pilot, also at FSL premises, will be realized with the first versions of user interfaces, devices, and the robotic platform. Each patient will be required to attend two sessions. Each session will be 1-hour duration

3. Summative phase. This final phase includes two sets of experiments, one at FHAG premises and one at the FZ. The objectives of these pilots are to validate the RADIO system and to provide results to support their validity.

[INSERT PARTICIPATION PROTOCOL HERE]

[START SAMPLE PARTICIPATION PROTOCOL]

Each training process will be executed in 2 sessions per week for 12 weeks (24 sessions). Duration of each session: 1 hour.

All the participants in the study will be followed during 9 months.

[END SAMPLE PARTICIPATION PROTOCOL]

You will not be paid for your participation in this research.

4. What are the possible benefits?

We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits may include:

- prolonging the time that elderly people can live independently at home by providing ICT service;
- delivering evidence of improvements in the quality of life of older people and their families;
- facilitating wide take-up of ICT based independent living related solutions across Europe.

5. What are the possible risks?

No side effects are expected for this experimentation based on using at home a robot which collect data about daily activities and mood and has been developed to help user during emergency situation trough an alert send to care-giver/doctors and helps users in remind some activities as take a medications.

6. What if new information arises during this project?

During the project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and your doctor will discuss whether this new information affects you.

7. Can I have other treatments during this project?

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your doctor about any changes to these during your participation in the research.

8. Are there alternatives to participation?

Participation in this trial is not your only option. Your other options may include the standard care. Discuss these options with your doctor before deciding whether or not to take part in this research project.

9. Do I have to take part in this project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are **free to withdraw** from the project at any time.

Your decision whether to take part or to not take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with [your Institution's name].

10. What if I withdraw from this project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

If you decide to leave the project, the researchers would like to keep the personal and health information about you that have been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you join the research project.

11. Could this research project be stopped unexpectedly?

This research project may be stopped for a variety of reasons before completion. These may include reasons such as:

- Unacceptable side effects;
- The intervention being shown not to be effective;
- The intervention being shown to work and not need further testing;

12. What else do I need to know?

What will happen to the information about me?

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law. All personal and medical

information will be treated securely and in accordance with privacy rules and with EU Data Protection and confidentiality laws.

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, the European Commission, [INSERT ORGANIZATION NAME] or as required by law. By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

What happens if I am injured as a result of participating in this research project?

The Hospitals and/or Care Centers involved in these trials unilaterally accept full and formal duty of care for patients involved in the study. For this reason, if you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

If, for any reason you cannot benefit of public health service, hospital care and treatment will be directly provided by the hospitals and care center leading the trials.

13. Consent

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to [name of Institution] concerning my disease and treatment that is needed for this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.

Participant's name (printed) ……

Signature Date

Name of witness to participant's signature (printed) ……

Signature Date

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed) ……

Signature Date

* A senior member of the research team must provide the explanation and provision of information concerning the research project.

Note: All parties signing the consent section must date their own signature.

14. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher or any of the following people:

Name:

Role: principal investigator (and 24-hour medical contact)

Telephone:

Name:

Role:

Telephone:

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name:

Position:

Telephone*:*

APPENDIX II

This appendix presents the Italian-language *Participant Information and Consent Form* that informs participants of the FSL trials about the project and explains the tests and treatments involved. This form is based on the English-language form in Appendix I.

FOGLIO INFORMATIVO PER LA RICHIESTA DI CONSENSO INFORMATO ALLA PARTECIPAZIONE AD ATTIVITA' DI RICERCA SCIENTIFICA ED AL CONSEGUENTE TRATTAMENTO DEI DATI PERSONALI

Gentile Signore/a ……..

la Fondazione Santa Lucia è un Istituto di Ricovero e Cura riconosciuto a Carattere Scientifico, che svolge, insieme all'attività di assistenza, quella di ricerca sanitaria e di formazione nel settore della riabilitazione neuromotoria e delle neuroscienze.

Nell'ambito di tale esercizio, è in corso una ricerca dal titolo "RADIO - Robots in assisted living environments: Unobtrusive, efficient, reliable and modular solutions for independent ageing".

Questo progetto di ricerca propone un sistema integrato per il monitoraggio e l'assistenza dell'anziano a domicilio. L'obiettivo principale è di fornire un sistema di monitoraggio non intrusivo all'interno dell'abitazione, la cui struttura lo renda parte integrante della vita quotidiana degli utenti; a tal fine RADIO utilizzerà un approccio caratterizzato da un assistente robot integrato con una casa domotica che da un punto di vista della relazione con la persona anziana possa essere assimilato a un animale domestico.

Il sistema RADIO nel suo insieme è composto da un robot mobile costituito da sensori in grado di rilevare movimento dell'utente, registrazioni audio, riconoscimento delle espressioni facciali e una interfaccia touch screen e/o vocale per il controllo del robot e della casa domotica.

In particolare le ADL monitorate dal sistema saranno: bagno, igiene personale, vestirsi (parte superiore e parte inferiore), deambulazione, trasferimenti, uso del bagno, mobilità a letto, mangiare.

Il riconoscimento delle emozioni sarà ottenuto attraverso l'analisi della raccolta di informazioni audio-visive basate (ad es. tonalità della voce, espressioni facciali,ecc).

I benefici previsti sono soprattutto legati alla possibilità di:

sviluppare un metodo per rilevare le attività della vita quotidiana e i disturbi del tono dell'umore

sviluppare un'interfaccia per l'utente anziano con i massimi requisiti di usabilità e facilità di fruizione;

sviluppare un assistente domestico per le attività di routine (portare oggetti, ricordare le medicine, portare da bere etc) all'interno di una casa domotica

I candidati che rispettano i criteri di inclusione saranno reclutati tra i pazienti ricoverati presso l'Unità Operatica C della Fondazione Santa Lucia. Lo studio sarà diviso in 2 fasi: una prima fase dedicata alla valutazione dell'interfaccia (tablet/smartphone) e una seconda fase dedicata alla valutazione dell'usabilità del prototipo (robot).

A ciascun partecipante della prima fase, dopo un periodo di training, sarà chiesto di provare un tablet e uno smartphone per la gestione di semplici attività domotiche quali accendere e spegnere una luce, bloccare e sbloccare una porta, controllare e regolare la temperatura ambientale, controllare il consumo energetico.

Inoltre, per i partecipanti anche alla seconda fase dello studio, sarà chiesto di essere affiancati dal sistema RADIO che dovrà monitorare le sue attività diarie. I risultati ottenuti dal sistema RADIO saranno confrontati con la registrazione effettuata dal care-giver attraverso un diario.

Ciascun soggetto potrà scegliere a una o entrambe le fasi.

La sua partecipazione è prevista della durata di circa 1 ora al giorno per un periodo complessivo di 1 settimana per ciascuna fase.

Non è previsto nessun effetto collaterale derivante dall'utilizzo del sistema.

Con il presente modulo Le viene proposto di prendere parte al programma di studio, il cui responsabile scientifico è la Dott.ssa Roberta Annicchiarico.

Se Lei deciderà di partecipare allo studio, sarà inserito, dopo la raccolta dei suoi dati da parte del personale addetto, nel gruppo di studio.

Durante lo studio verrà effettuata una valutazione multidimensionale consistente nella somministrazione di alcuni questionari e di scale di valutazione. La valutazione complessiva richiederà circa 1 ora e verrà effettuata all'inizio e alla fine dello studio.

Non è previsto nessun pagamento per la partecipazione a questa sperimentazione.

Il medico referente, nella persona della Dott.ssa Roberta Annicchiarico, sarà sempre a Sua disposizione per qualsiasi chiarimento, La informerà prontamente di qualunque notizia si renda disponibile durante lo studio e provvederà a sospendere la Sua partecipazione allo studio qualora ciò risulti nel suo interesse, comunicandoLe i motivi di tale sospensione.

Nel corso dello studio al quale prenderà parte, Lei sarà assicurato a copertura di eventuali danni da esso derivante.

La partecipazione allo studio non comporta per Lei alcun aggravio di spesa.

Lo studio è stato approvato dal Comitato Etico Indipendente della Fondazione Santa Lucia ed il suo svolgimento ed i suoi risultati sono monitorati dallo stesso Comitato.

Lei ha il diritto di non partecipare allo studio che Le viene proposto. Questo non comporterà assolutamente una minore assistenza nei Suoi confronti e Lei sarà in ogni caso sottoposto al miglior trattamento possibile per il suo stato di malattia.

Anche nel caso di accettazione a partecipare allo studio, Lei ha il diritto di ritirarsi dallo stesso in qualsiasi momento, senza essere obbligato a fornire alcuna giustificazione.

Si precisa che i risultati dello studio verranno portati a conoscenza della comunità scientifica ed i dati raccolti durante la sperimentazione non potranno rimanere di proprietà di singoli o gruppi che li possano utilizzare secondo il loro esclusivo interesse.

La procedura dello studio garantisce, peraltro, la riservatezza dei Suoi dati personali con riferimento al relativo Codice (D.lgs. del 30 giugno 2003, n. 196), ai sensi del cui art. 13 si sottopone la seguente informativa.

in conformità alle disposizioni del Codice in materia di protezione dei dati personali (di seguito "Codice"), la Fondazione Santa Lucia La informa che intende svolgere attività di trattamento di dati personali (di seguito "Dati"), anche sensibili , che La riguardano.

FINALITA' E MODALITA' DEL TRATTAMENTO DEI DATI

I Dati forniti vengono acquisiti e trattati nel rispetto della normativa sopra richiamata, con il supporto di mezzi cartacei, informatici o telematici atti a memorizzare, gestire e trasmettere i dati stessi e comunque mediante strumenti idonei a garantire la loro sicurezza e riservatezza, nel rispetto delle regole fissate dal Codice, per le finalità della ricerca in precedenza descritta riguardo agli obiettivi, alle procedure, ai benefici ed rischi della partecipazione, all'impegno operativo e temporale richiesto

NATURA DEL CONFERIMENTO E CONSEGUENZE DI UN EVENTUALE RIFIUTO

L'eventuale rifiuto di fornire i Dati funzionali all'esecuzione della ricerca su menzionata, non comporta alcuna conseguenza relativamente ad eventuali trattamenti terapeutici in corso, salva l'eventuale impossibilità di dare seguito alle operazioni connesse alla ricerca.

Lei è libero/a di non partecipare alla ricerca o di ritirarsi dallo stessa anche senza preavviso o motivazione. Qualora, durante la ricerca, divengano disponibili dati che possano influenzare la Sua volontà di continuare Lei sarà tempestivamente ed opportunamente informato e, se necessario, Le sarà richiesto nuovamente il Consenso Informato a proseguire il trattamento in corso

COMUNICAZIONE DEI DATI

I Dati potranno inoltre venire a conoscenza dei responsabili della cui opera la Fondazione Santa Lucia si avvale nell'ambito di rapporti di esternalizzazione per la fornitura di servizi, nonché dei responsabili e degli incaricati del trattamento dei dati per le finalità di cui alla presente informativa, l'elenco aggiornato dei quali è a disposizione presso la sede della Fondazione Santa Lucia.

I Dati relativi ai risultati della ricerca sono strettamente confidenziali e soggetti ad anonimato. I risultati potranno essere portati a conoscenza di terzi o pubblicati, ma escludendo ogni possibile riferimento personale al paziente

DURATA DEL TRATTAMENTO

I Dati verranno trattati dalla Fondazione Santa Lucia solamente per la durata della ricerca prevista in 3 anni.

DIRITTI DELL'INTERESSATO

L’art. 7 del Codice riconosce all’interessato numerosi diritti che La invitiamo a considerare attentamente. Tra questi, Le ricordiamo sinteticamente i diritti di:

- ottenere la conferma dell’esistenza o meno dei Dati che lo riguardano, anche se non ancora registrati, e la loro comunicazione in forma intelligibile;
- ottenere l’indicazione dell’origine dei Dati, delle finalità e modalità del trattamento, degli estremi identificativi del titolare, dei responsabili, dei soggetti o delle categorie di soggetti ai quali i Dati possono essere comunicati o che possono venirne a conoscenza in qualità di responsabili o incaricati;
- ottenere l’aggiornamento, la rettificazione o l’integrazione dei Dati (qualora vi sia un interesse in tal senso) ovvero la cancellazione, la trasformazione in forma anonima o il blocco dei dati trattati in violazione di legge, nonché l’attestazione che tali operazioni sono state portate a conoscenza di coloro ai quali i Dati sono stati comunicati o diffusi;
- opporsi, in tutto o in parte, al trattamento dei Dati che lo riguardano per motivi legittimi ovvero per fini di invio di materiale pubblicitario o di vendita diretta o per il compimento di ricerche di mercato o di comunicazione commerciale.

Lei, per l'intera durata del trattamento, potrà chiedere informazioni o porre domande al medico circa i dati acquisiti nel corso della sperimentazione e circa l'andamento della stessa relativamente al suo caso; allo stesso modo, al termine della ricerca, se richiesto, i risultati che La riguardano saranno comunicati a Lei ed al suo medico di base.

TITOLARE DEL TRATTAMENTO

Titolare del trattamento è la Fondazione Santa Lucia, Via Ardeatina, n. 306 , Roma.

Per qualsiasi ulteriore informazione, chiarimento e comunicazioni è a disposizione il responsabile dei dati nella persona del responsabile della sperimentazione dott.ssa Roberta Annicchiarico".

Dott. Responsabile della sperimentazione: Dott.ssa Roberta Annicchiarico

Reparto: UOC

Roma, lì 08 giugno 2015.

MODULO CONSENSO INFORMATO

Io sottoscritto ……..……., familiare del paziente…… dichiaro di aver preso visione del protocollo concernente lo studio “FATE: Rilevatore di cadute per anziani” che si svolgerà presso la Fondazione Santa Lucia.

In particolare dichiaro

- di aver ricevuto, all'interno di tale foglio illustrativo, l’informativa prevista dall’articolo 13 del D.lgs. 196/2003 riguardo al trattamento dei dati personali.

- di avere avuto a disposizione tempo sufficiente per poter leggere attentamente e comprendere quanto contenuto nel suddetto foglio illustrativo.
- di aver ricevuto dalla Dott.ssa Roberta Annicchiarico che opera presso la UOC esaurienti spiegazioni in merito alla richiesta di partecipazione allo studio.
- di essere stato informato del diritto di ritirarmi dalla ricerca in qualsiasi momento, senza dover dare spiegazioni e senza compromettere l'assistenza medica futura.
- Di aver ricevuto il nominativo del Dott.ssa Roberta Annicchiarico come medico referente per qualsiasi ulteriore chiarimento o informazione relativa alla sperimentazione
- Di aver avuto modo di esporre le mie considerazioni e di domandare ulteriori precisazioni, nonché di avere avuto il tempo necessario per prendere una decisione ponderata e non sollecitata.

Pertanto, sono consapevole delle attività previste e delle modalità di una mia adesione.

Ciò premesso dichiaro

di acconsentire ☐

di non acconsentire ☐

a partecipare allo studio ed al conseguente trattamento dei miei dati personali sensibili.

cognome e nome della persona	firma della persona
_____	_____

oppure

cognome e nome del rappresentante legalmente valido	firma del rappresentante legalmente valido
_____	_____

cognome e nome del medico che raccoglie il consenso	firma del medico che raccoglie il consenso
_____	_____

NB: il presente modulo è valido solo se accompagnato dal corrispondente foglio illustrativo

APPENDIX III

Ethical Committee approval.

FONDAZIONE SANTA LUCIA
ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO
Ospedale di rilievo nazionale e di alta specializzazione per la riabilitazione neuromotoria
00179 Roma -Via Ardeatina, 306 - Tel +39 06515011 - Fax +39 065032097 - www.hsantalucia.it
COMITATO ETICO

Ufficio di Segreteria
Resp. : Dr. Stefano Paolucci
Segreteria: Sig.ra Elisa Battisti
- tel. 0651501491
- fax 0651501453
e-mail comitatoetico@hsantalucia.it

Dr.ssa Roberta Annicchiarico
Fondazione Santa Lucia
Sede

Prot. CE/PROG.511 26-06-15

Visti gli atti propri del Comitato Etico operante presso la Fondazione Santa Lucia di Roma, con sede in Via Ardeatina 306, 00179 Roma

Si comunica

in data 22 Giugno 2015 si è svolta la riunione del Comitato Etico, durante la quale é stata esaminata tra l'altro, la proposta di studio da Lei avanzata dal titolo **"Robots in assisted living environments: Unobtrusive, efficient, reliable and modular solutions for independent ageing".**

Dopo la discussione il Comitato decide di approvare lo studio all'unanimità.

Distinti Saluti.

Per la Segreteria
Elisa Battisti

APPENDIX IV

Hardware certifications for the RADIO robots and the mobile devices used by the end users.

DECLARACIÓN CE DE CONFORMIDAD

Robotnik
AUTOMATIZACIÓN Y ROBOTIZACIÓN

La empresa: ROBOTNIK AUTOMATION SLL
C/ Berní y Catalá, 53 bajo
46009 - VALENCIA

declara bajo su única responsabilidad que la máquina,

Denominación: Turtlebot2
Año de Fabricación: 2015

se halla en conformidad con todas las disposiciones aplicables de:

- La Directiva de Máquinas 2006/42/CE (DOUE L-157.09-06-2006).
- La Directiva de Compatibilidad Electromagnética 2004/108/CE
- La Directiva de Material Eléctrico de Baja Tensión 2006/95/CE

y se han aplicado la normas:
- UNE-EN 61439-1:2011 / AC:2013

En su nombre D. Roberto Guzmán Diana en calidad de Administrador, firma la presente declaración:

Valencia, a 5 de Mayo de 2015

Firma

Robotnik
ROBOTNIK AUTOMATION, S.L.L.
C.I.F. B-97223630
C/ Berni y Catalá, 53 • Tel./Fax 96 338 38 35
46019 VALENCIA • www.robotnik.es

SAMSUNG ELECTRONICS

Declaration of Conformity

Product details

For the following
Product : GSM WCDMA LTE BT/WiFi Portable Device
Model(s) :SM-T535

CE 0168

Declaration & Applicable standards

We hereby declare, that the product above is in compliance with the essential requirements of the R&TTE Directive (1999/5/EC) by application of:

SAFETY	EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011	
SAR	EN 50566 : 2013 EN 62479 : 2010	EN 62209-2 : 2010
EMC	EN 301 489-1 V1.9.2 (09-2011) EN 301 489-24 V1.5.1 (10-2010) EN 301 489-7 V1.3.1 (11-2005) EN 55024 : 2010	EN 301 489-17 V2.2.1 (09-2012) EN 301 489-3 V1.6.1 (08-2013) EN 55022 : 2010/AC:2011
RADIO	EN 300 328 V1.8.1 (06-2012) EN 300 440-2 V1.4.1 (08-2010) EN 301 893 V1.7.1 (06-2012) EN 301 908-1 V6.2.1 (04-2013) EN 301 908-2 V5.4.1 (12-2012)	EN 300 440-1 V1.6.1 (08-2010) EN 301 511 V9.0.2 (03-2003) EN 301 908-1 V5.2.1 (05-2011) EN 301 908-13 V5.2.1 (05-2011) EN 301 908-2 V6.2.1 (10-2013)

and the Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment by application of EN 50581:2012.

The conformity assessment procedure referred to in Article 10 and detailed in Annex[IV] of Directive 1999/5/EC has been followed with the involvement of the following Notified Body(ies):

TÜV SÜD BABT, Octagon House, Concorde Way, Fareham,
Hampshire, PO15 5RL, UK*
Identification mark:0168

Representative in the EU

Samsung Electronics Euro QA Lab.
Blackbushe Business Park Saxony Way,
Yateley, Hampshire GU46 6GG, UK*
2014.03.18

(Place and date of issue)

Stephen Colclough / EU Representative

(Name and signature of authorized person)

* This is not the address of Samsung Service Centre. For the address or the phone number of Samsung Service Centre, see the warranty card or contact retailer where you purchased your product.