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D1.3 Complete pilot definition

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Authors: A. Rodriguez (NUIG), R. Annicchiarico (FSL)

[1] R = Report, P = Prototype, D = Demonstrator, O = Other

[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)

Revision history

Date	Partner	Description	Name
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6/09/12	FSL	Improvement of Annex 2	Roberta Annicchiarico, Alessia Federici
6/09/12	UPC	Final approval	J. Cabestany

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Glossary

Adverse event (AE) is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs in subjects, users or other persons.

Co-investigator: Additional investigator designed by the Principal Investigator.

Case Report Form or CRF: paper or electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each participant in a clinical trial are held and/or documented in the CRF, including adverse events.

Control period: follow-up period in which the participants are NOT using the FATE system.

Convenience sampling: is a type of non-probability sampling which involves the sample being drawn from that part of the population which is close to hand. That is, a population is selected because it is readily available and convenient.

Device Deficiency: An inadequacy of the device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies may include malfunctions, user errors and inadequate labelling.

EC: Ethical Committee.

Effectiveness: In medicine, effectiveness relates to how well an intervention works in practice, as opposed to efficacy, which measures how well it works in clinical trials or laboratory studies.

FATE: Fall Detector for the Elder.

IC form: Informed Consent Form.

Intervention period: follow-up period in which the participants are using the FATE system.

Monitor: Designated by the sponsor to observe and assess the quality of the clinical study.

Principal Investigator: Principal Investigator (PI) is the responsible person for the study in each country. The role of the Principal Investigator is to implement and manage the clinical investigation as well as ensure data integrity and the rights, safety and well being of the subjects involved in the clinical investigation.

Recruitment Coordinator: designated by the sponsor to coordinate inclusion of participants and ensure recruitment stratification.

RRF: Recruitment Report Form.

Safety: to what extent the intervention does not produce adverse health outcomes (adverse events).

Sponsor: the overall sponsor of the study is the FATE consortium. The sponsor in each country will be the local health entity of the FATE consortium.

Validity: Precision. It identifies how close a result is to the true value.

Wash out period: It is the study period between the intervention and control periods where no monitoring is performed.

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1. Introduction

The world and especially European population is aging rapidly, so there is increasing interest in new social and health care technology and services available for future generations of elderly. The development of new information and communication technologies enables the development of many new telehealth and telecare systems; however various barriers to implementation hamper the scale implementation of such systems.

It is remarkable that among the many implementation difficulties there is a lack of knowledge in key areas such as *validity*, *efficacy* and *safety* of these technologies, which also makes it very difficult to estimate the cost benefit of this new kind of health care.

The lack of knowledge in these areas is not due to a lack of a significant body of evidence, or a lack of well designed studies of adequate sample size. It is also not due to the use of proper data collection methods and well-selected measurements and outcomes.

Therefore in order to address these problems this document introduces a scientific protocol that will address these issues by allowing the Fall Detector for the Elder (FATE) system to be assessed in multiple domains, including end user perspectives and stakeholder's perspectives. This protocol involves the use of a tailored study design capable of assessing system reliability, safety and effectiveness. This protocol has been carefully designed to provide evidence in relation to the problem domain areas previously mentioned. The protocol does this by targeting and assessing these problem areas, and will therefore contribute to overcoming these barriers to system implementation in the telehealth market.

1.1. Name and intended use of investigational system

The FATE system is a real time alarm system capable of detecting falls both inside and outside the home, for the purposes of communicating these fall events to a family member or a call-emergency service.

As depicted in Figure 1, the main elements of the system are a highly sensitive, water resistant, fall detector (comprising an accelerometer based device incorporating a complex specific fall detection algorithm), and a communication layer based in wireless technologies. The system also includes a bed presence sensor that helps to detect falls at night, and an optional robotic walker (i-Walker), for those users who suffer with gait problems. All the fall incidences and measurements taken by the system are stored in a server, and therefore serve as monitoring data for carers or doctors.

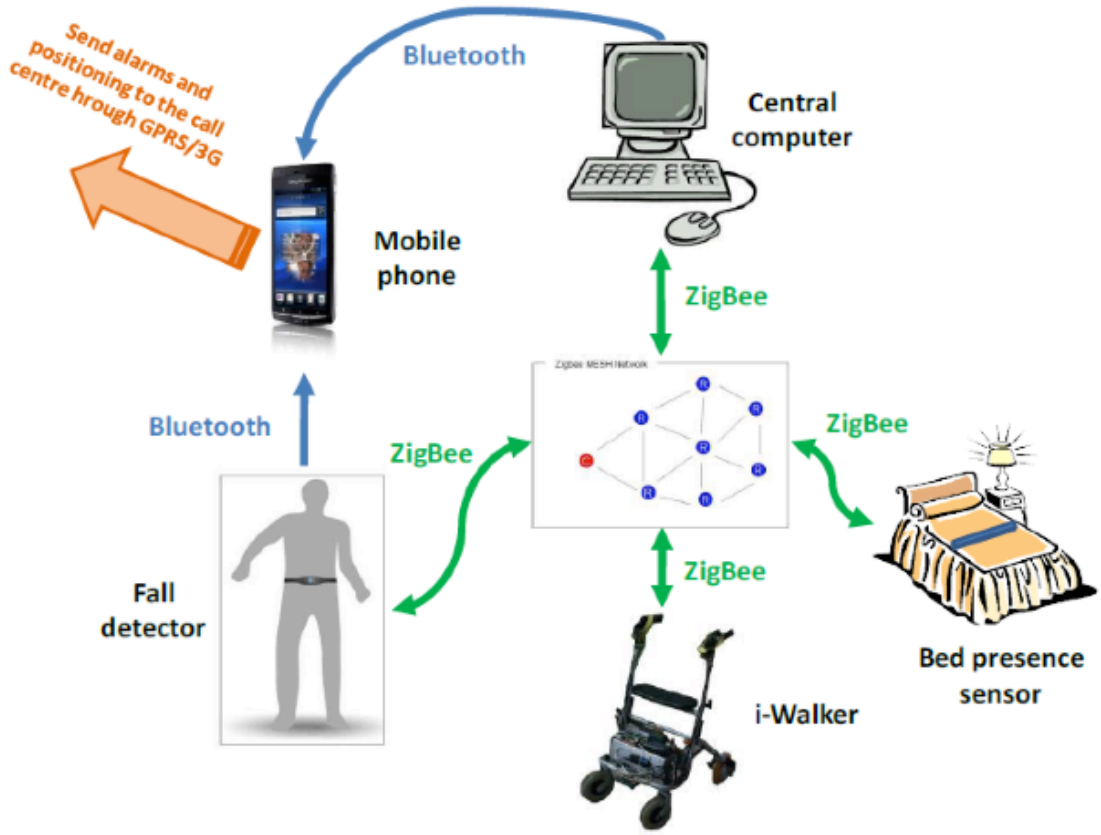


Figure 1. FATE system architecture.

The optional robotic i-Walker will be tested in a specific study protocol that is annexed to this document (Annex 1).

2. Summary of the known and potential risks and benefits

2.1. Anticipated risks

The purpose of the FATE system to be used in this study is to provide round the clock fall detection independent of location, and to communicate these fall events in real time to a family member or a call-emergency service. The only risks that can be anticipated are skin reactions to the fall detector and the belt that attach it to the body, and any inconvenience caused by false alarms. Biocompatibility of the belt and the electrical and electromagnetic safety of the sensor has been ensured and tested according to the applicable rules.

False negatives are not considered a potential risk of the system, as the system is not substituting any other method for fall detection in this study. Thus, the lack of detection of a fall does not mean any added harm to the participant, comparing with those people not wearing the system.

2.2. Potential benefits

The FATE system can potentially reduce the long lie syndrome, due to the automatic communication of a fall, and a possible reduction in the time to rescue. Thus the system may reduce rabdomiolisys, kidney failure and the other components of this syndrome.

Most falls that occur do not result in severe harm to the faller, but they are announcing the risk of impending injurious falls that can eventually occur. In the clinical setting a person's falls history is considered a strong predictor of future falls and harm. The falls history helps the clinician to identify individuals of high falls risk. As the FATE system detects falls and stores the history of falling, it is also a useful tool to stratify the fall risk and to identify recurrent falls in participants that will benefit the participant through the use of preventive interventions that decrease falls risk. In this sense the system contributes towards reducing future falls. Where the i-Walker is used it can also contribute towards reducing fall risk by functioning as a technical aid to improve gait and balance, and therefore reduce the number of future falls.

The FATE system can also contribute towards alleviating the *Fear of Falling* syndrome, which frequently leads to social isolation, functional self-restriction and functional loss. As the system raises an alert when a fall is detected, many of the users may feel self-confident when walking and moving normally when wearing the system.

Overall the FATE system may improve the quality of live of the users and their relatives.

3. Hypotheses

The following hypotheses are considered in this study:

- The FATE system is a stable, reliable and scalable system ready for implementation and use in real conditions.

- Falls detected by the system are valid so the number of false positives and false negatives is low enough for a system useful in real conditions.

- The FATE system can reduce the incidence of long-lie syndrome and fear of falling, thus it increases autonomy and quality of life. The FATE system can detect recurrent falls in people and is therefore a useful instrument to raise awareness of the problem and in turn trigger the pertinent corrective actions. Thus the FATE system is able to reduce subsequent falls and their consequences (fractures, fear of falling…). In addition to this the system can potentially reduce fear of falling and therefore increase activity and autonomy, which could eventually lead to an improvement in balance and gait (balance and gait is best preserved in active people and can help an individual to maintain independent living).

- The FATE system is safe and has no relevant adverse effects, which could harm the participant.

- The FATE system has a positive benefit-cost and cost-effectiveness balance.

4. Objectives

This section provides a summary of the objectives to be attained by the present study. The variables used to quantify these objectives will be explained in detail in section 10.

1. To measure system's performance

1.1. System's stability.
1.2. System's transmission reliability.
1.3. System's data reliability (internal validity). It is actually not a goal of the study, since it affects the fall sensor and it has been already verified by the sensor manufacturer.

2. To measure system's validity

2.1. Validity for fall detection.
2.2. Validity for fall's risk estimation.

3. To measure system's effectiveness

3.1. Fall detection.
3.2. Reduction of long-lie syndrome.
3.3. Increasing activity and functional capacity.
3.4. Improving gait and balance.
3.5. Improving quality of life.
3.6. Increasing the number of interventions for fall risk reduction.
3.7. Increasing contacts and surveillance by primary care physicians.

4. To estimate system's safety

5. To measure usability and user satisfaction

5.1. Usability of the whole system.
5.2. Usability of each subsystem.

6. To estimate system's efficiency

6.1. To estimate system's cost.
6.2. To estimate system's cost-benefit.
6.3. To estimate system's cost-effectiveness.

7. To measure in what extent the system developed by the project is scalable.

8. To gather users' and stake-holders' opinions on the system, its utility. To gather data for creating or evaluating a business plan.

5. Study design

This is a multicentre and multinational experimental clinical trial with a cross over study design.

All the participants in the study will be followed during their 12-month period of participation. All participants will use the FATE system for an **intervention period** of six months, and also for a separate **control period** of 6 months where the participant will be under "*standard care*" (the usual health care in their area), as depicted in Figure 2. Therefore each participant will be monitored (under the study measurements and observations), both when using the system and when not using the system. This study design allows each participant to be his or her own "control" for statistical analysis purposes.

In a study of this kind the order in which the participants receive the intervention or the control period may affect the results. In order to avoid this effect, half of the participants will participate in the control period first, and after this initial control period they will use the FATE system for the intervention period. Contrary to this the other half of the participants will participate in the study the other way around, and will use the system for the intervention period first and then enter the control period.

Some of positive or negative outcomes of the system's use may be long term after using the system. This means that people using the system for the first six months could still experience the system's possible benefits or hams that occurred during the control period. For this reason there will be a four-month wash-up period between the intervention and control periods (during the wash-up period no measurements or contacts with the participants will exist). Additionally, the mere "observation" of the users by the researchers could have positive or negative effects on the users' behaviour that also may last for long time. The wash out period is also needed for those who start the study with the control period first as they won't be using the FATE system but will be participating in the study. The wash out period will allow them to return to their basal set point that existed before their participating in the study.

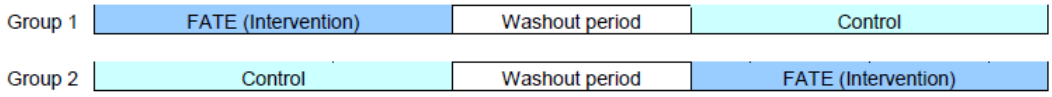


Figure 2. Temporal organisation of the study.

Effectiveness, efficiency and safety outcomes will be estimated by comparing their incidence during the "*control period*" and the "intervention period". All the other outcomes will be measured while the participants use the system during the intervention period.

6. Study timeline and work plan

6.1. Study preparation phase

Before fieldwork starts, a preparatory phase is necessary in order to prepare the devices for implementation. This period is also necessary to obtain ethical approval from relevant ethics committees and regulatory agencies. After ethical approval has been secured the preparatory phase also allows us to recruit users, install the system in the houses and provide the necessary training for the end users and the researchers.

Figure 3 shows the timeline of these previous tasks.

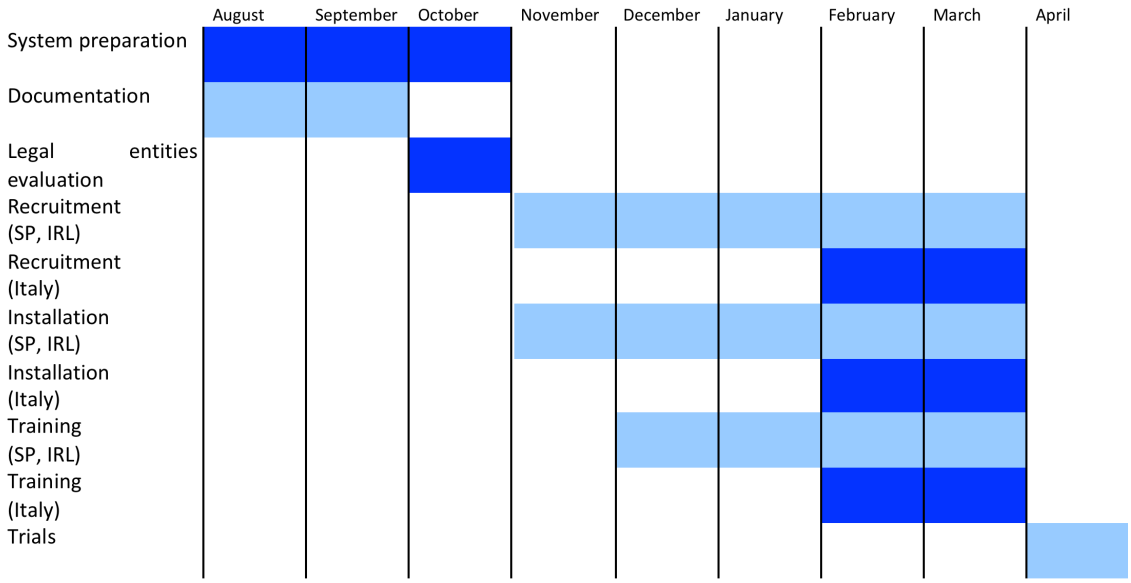


Figure 3. Timeline for the study preparation phase.

6.2. Field work

The fieldwork of the study will last 16th months and will take place between April 2013 and July 2014.

Observation periods:

- April 2013 through September 2013.
- February 2014 through July 2014.

The washout period:

- October 2013 through January 2014.

Figure 4 summarises the timeline of these tasks.

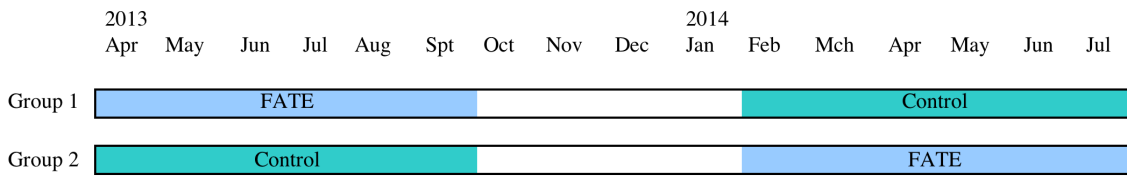


Figure 4. Timeline of the fieldwork.

7. Study settings

This is an international study that will be conducted in three European countries: Spain, Italy and Ireland.

In Spain, the system will be implemented at seniors home and at senior nursing homes. Regarding the latest mentioned, the FATE project will be deployed in two facilities. One of them is placed in the area of Barcelona and the other one (nowadays there are three candidates) will be placed in the area of Barcelona, Zaragoza or Madrid.

Also an important number of seniors will participate at the FATE at home pilot. Seniors will be enrolled from the Mataró area. Mataró is a small city near Barcelona and this also includes the surrounding villages. All the participating seniors will be followed by specialists of the gerontology unit of the Consorci Sanitari del Maresme (located in Mataró).

In Italy, the FATE project will involve three Social Districts of Marche region, including 36 municipalities belonging to three social districts: S. Ginesio, Severino and Camerino. The municipalities are located in a mountainous area of Marche region where some of the smallest are quite isolated from the others and my face communication problems and difficulties to access the health services (especially during the winter)

In Ireland FATE will be deployed in the North Clare, Galway City and South Galway region. This would include the small towns of Lisdoonvarna, Ennistymon, Gort, Miltown Malbay and Loughrea. It also includes rural dwellers in these areas.

8. Service description in each study site

In each pilot site the system will be integrated in an existing model of care, thus it will be possible to examine the performance and level of acceptance of the system within each model in three different contexts.

Each pilot site will define specific action protocols for care and emergency management, according to the local circumstances and resources. However, the three sites will follow the common research themes identified in the procedures defined in this document, and will use the same measurements and instruments. This will facilitate addition, coordination and comparison of data between the three pilot studies.

8.1. Spain

In Spain the system will be implemented in two different scenarios, to monitor two different profiles of users: community dwelling people and nursing home residents.

Community dwelling people

In the first scenario, the FATE system will be integrated in an existing infrastructure for a 24h emergency call service. The regular procedure in this service is as follows: from the time of reception of the call, the call operators use a computer system. This tool allows them to locate, classify, determine, answer and record all data on the service. The system has a GIS (Geographic Information System) of towns, villages and streets to assist in the proper location

of the incident. Classification and response are determined by the protocol (supported by software) that has been developed, agreed, reviewed and updated periodically by staff. Depending on the input regarding the reason for the call and symptoms, a response is proposed by the system based on closed protocol. This contains a referral for medical consultation and / or activation of resource assistance. Participant identification, location, time and reason for calling, data required for classification, and actions performed are all recorded.

In the pilot study alert is addressed directly to the call operator. In this case is not necessary to gather information about identification, location and reason for calling. Medical team will decide if it is necessary to send an ambulance or if it's a false alarm. When a fall event will be detected by the FATE service, the regular specific process the emergency service (SEM) uses when they receive an alert that will be also used.

Nursing home residents

In this scenario, we must consider two important issues. On one hand the FATE system will be integrated with the locating and identifying solution and on the other hand the FATE system will work in an assisted environment. This means that when a fall detection alert occurs, staff members will know in real time who has fallen and also where they have fallen. In this instance the staff members (physician assistant, nurse or physician) who attends the elder fallen must decide the next step to do according the internal actuation protocol of the facility. Fall severity will dictate whether the elder will be treated in the same facility or will be taken to the hospital. All the information regarding fall event will be gathered for the staff members for further study and analysis.

8.2. Italy

In Italy a specific Call Centre will be created for the project. This Call Centre will be located in the Nursing Home in Camerino city centre and all the older users will be living in the area of reference.

In accordance with the procedures described in deliverable D1.1, if and when an alarm arrives to the Call Centre, the Operators will take care of the situation. After fall validation the Operator will contact the person/s who has previously agreed to be informed in case of fall (i.e. relatives, neighbours, friends, 118 in case of emergency). These aspects will be gathered in a dedicated protocol. The process is graphically represented in the Flow Chart "*FATE service model in the pilot sites*" – in deliverable D1.1.

An important aspect will be the "client file" which will be elaborated by the call centre; its features (protocol, actions, procedures, feedback, data sharing, etc.) will be described in deliverable D2.2.

8.3. Ireland

During the pilot, Tunstall Emergency Response will provide the services of its monitoring centre to process all alarms sent from the FATE fall detection service. When a fall is detected by the FATE fall detector and notified to the monitoring centre the following steps will be followed.

An incoming call to the monitoring centre will automatically open the client details so the monitoring operators know immediately whom they are dealing with and what their medical

history is. The location of the client will also be available – either at home or outside the home. The operator will then attempt to call the client by either their mobile phone or home phone to check if they need help.
If the client can let the operator know that they are ok and do not need help the call is recorded on the client history file and the call closed. It will be possible to identify and record false alarms at this stage.

If the client cannot be reached, or they have confirmed they need help, then the operator will proceed to call the first designated contact on file.

If that contact can be reached, the monitoring centre operator will provide them with time of the fall and the location of the client. If they are in a position to respond the call can be closed, updating the client's history file.

If the contact cannot be reached then the above step is repeated for all other contacts listed on the client file. In Tunstall Emergency Response we recommend our clients provide a minimum of 3 contacts on their file. These should be family/friends or carers who have a key to the client's home in case of emergencies.

Emergency services (police, etc.) will only be called if none of the listed contacts can respond, or if the client themselves or one their contacts specifically request them. Emergency service will be provided with the client name and the time and location of the fall.

The monitoring operator will not close the call until they are satisfied that the client is safe. At the end of each call the client history is updated with details of all the steps followed.

9. Study population

The reference population is all the European elderly persons at risk of falling.

9.1. Number of participants

The study will be conducted on 175 user-groups. Each *user-group* comprises the elderly participants, their contact person (available relative or friend) and the responsible telecare operator/s.

The number and kind of user-groups in each country will be distributed as follows:

Spain:

- 50 nursing home residents
- 25 community dwelling participants

Italy:

- 50 community dwelling participants

Ireland:

- 50 community dwelling participants

9.2. Eligibility criteria

Criteria for the elderly people:

Inclusion criteria:

- Older than 64 years old.
- At least 1 fall in the previous 6 months or alternatively a high enough risk of fall determined by the responsible of the local recruitment.
- Ability to walk without human assistance indoors.
- 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.
- Community dwelling participants will have a family member or relative available (not mandatory for nursing home residents).

Exclusion criteria:

- Lack of any of the following technical conditions:
  - GSM coverage at home.
  - Home that allows ZigBee network coverage.
  - One free Wall power plug in the bedroom.
  - Around 3-4 free Wall power plugs distributed through the home in order to facilitate ZigBee network coverage.
- Carriers of implanted electronic devices: cardiac pacemaker, implantable automatic defibrillator, etc.
- Known mental disease, such as dementia, according to clinical criteria -DSM-IV-TR and MMSE score ≤24 or neuropsychiatric disorders.
- Acute medical conditions.
- Chronic condition leading to more than one or more hospital admissions in the last year.
- Participating in another clinical trial.
- 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.
- Unable to operate the FATE system after 2 training sessions.

Contact person / Family member / Informal carer:

- Should be a person related to the participant, who has had a previous known role in the care of him/her.
- Enough autonomy to contact with the elder in case of need and contribute to the decision making process in case of emergency.
- 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.

Telecare operators:

- Complete training in system operating and protocol guidelines.

- 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.

9.3. Sampling procedure / recruitment

The sponsor in each area will be responsible of sampling recruitment. The sample will be selected by convenience sampling of the population already using telecare services or other social services in each local area of the study. For identifying the participants, databases of the local health providers may be used. Once they have been selected, a family member, a relative or a neighbour will be contacted and offered to participate in the study.

The sponsor in each country will make available a suitable number of tele-operators (caretakers) for covering the needs of the trials in each region, including all the study hours.

In Spain, the recruitment of participant's will be in charge of the geriatric unit of the Consorci Sanitari del Maresme (located in Mataró), where doctors will assess participants for the possible inclusion to the trial. SEM existing call operators will report any intervention performed to a participant to the clinicians in charge of the follow-up of the participant.

In Ireland, TER will lead the recruitment process with the assistance of local Health Service Executive staff. TER also has an existing client base and will engage it if necessary to assist the recruitment process based upon the study criteria.

In Italy, COOSS will recruit in close collaboration with the Social District Coordinator and Social Workers/professionals of the territory. The FATE users will be identified among elderly who benefit from the traditional social services provided by the Local Bodies, not linked to telecare solutions yet. The recruitment will be carried out among the users benefitting from the following two services:

- Home care services: these services are provided to frail older people by operators/carers who periodically visit the users at their own homes. The frequency and the type of service (basic housekeeping, personal care and social activities) depend on the different users' needs and conditions. The purpose is to allow the users to live in their own homes as long as possible. The home care service supports about 350 older people with in the area of reference.
- Social Taxi: this service responds to the need for mobility of older people, offering a transport service for particular needs in an area where isolation and lack of infrastructures is more prevalent than elsewhere. The social taxi in the area of reference serves around 300 persons.

Candidates will be contacted by a member of the research team corresponding to their area, who will appoint them for a screening phone call and the screening visit, where it will be verified whether they meet the inclusion criteria while not meeting the exclusion ones (see procedures: screening visit)

The overall sample (including the sample of each pilot site) will be stratified according the habitat size (rural town communities with less than 10,000 residents will be included), and residency (125 participants will be Community dwelling, living in their own home, while 50 participants will live in nursing home facilities) to ensure enough representation of each of these features of the population. This stratification will be ensured by the study recruitment coordinator, who will be notified of basal characteristic of each participant included in the study

in any country. If necessary the recruitment coordinator will provide instructions to country sponsor to correct the stratification deviations.

10. Variables and instruments

This section lists all the variables that had to be measured in order to achieve the objectives of the study and to assess the outcomes. Each variable had to be measured by the means of one or several instruments or indicators, which also are specified below. When pertinent, the bibliographic reference of the instrument is added.

The section describes *what* is going to be measured. The "procedures" section of this protocol explains *when* each variable will be measured during the study. The Case Report Form includes specific instructions on how to uses the indicators and questionnaires.

The "statistical analysis" section describes how the data related to each variable will be analysed.

10.1. System's performance variables

System's stability:

- Number of times the system has to be reassumed.
- Number of technical interventions and intervention type.
- Time without assistance.

System's transmission reliability:

- Number of data not reaching the server (Packet Error Rate tests).
- Number of false or erroneous data reaching the server.

10.2. Validity of the system's data

- Number of true falls (falls diary, weekly telephonic interview).
- Number of falls detected by the system.

10.3. Effectiveness outcomes of the system

- Falls reduction (number of falls).
- Fear of falling (Falls Efficacy Scale [1]).
- Long lie (Time to rescue).
- Balance and gait? (Tinetti's scale [2]).
- Increasing activity (Stanford seven-day physical activity recall questionnaire [3]).
- Increasing functionality (Barthel index [4], Lawton index [5] AADL questionnaire, Up & Go [6]).
- Number of contacts with the caretaker.
- Contacts with emergency services.
- Contacts with GP.
- Number of preventive measures implemented.

- Number of rehab prescriptions.
- Quality of live (SF-36) [7].
- Time devoted to care by the contact person, when applicable.

10.4. Participants' safety issues

- Number of adverse effects.
- Severity of adverse effects.
- Number of participants leaving the study due to adverse events.
- Number of participants withdrawn of the study due to adverse events.

10.5. Usability and user satisfaction

- QUEST (Quebec User Evaluation of Satisfaction with Assistive Technologies) [8] – participants and teleoperators.
- Semi-structured diary on usability for participants and teleoperators.
- Contact person satisfaction: structured questionnaire.

10.6. Stakeholders satisfaction, perceptions of professionals

- Structured interview for stakeholders.

10.7. Scalability

- Data volume per user during the experiments.

10.8. Control variables

- Demographic data.
- Social data (cohabitation, responsible).
- Drug regimen modifications (weekly telephonic interview).
- Minimental State Examination [9].
- Fall risk: Number of falls in the last 6 months (as reported by the participant in a traditional interview).

10.9. Identification data

- Name.
- Telephone number.
- Address.

11. Study equipment.

This section lists the equipment that will be used to test the FATE system in community dwelling participants. In the nursing home pilots the system will be integrated with the existing identification and location system, being some components of both systems integrated in a single device. The equipment used in the nursing home is described in Annex 1.

The optional i-Walker of the FATE system will be tested in a separated study, which is described in Annex 2.

11.1. The Personnel Computer PC

Shuttle XS35-703 V2, Intel Atom 525 (1.8 GHz), Intel GMA3150 Graphics, 2GB RAM, 160GB HDD.

Figure 5. Personnel Computer view

11.2. The Smartphone

Samsung Galaxy Mini (Wi-Fi, Bluetooth 2.1, 280 MB RAM, Android 2.2).

Figure 6. Selected Smartphone view

11.3. The USB to ZigBee adapter

XU-Z11 from Digi. Permits the PC to control de indoors ZigBee network.

Figure 7. Selected USB to ZigBee adapter for PC

11.4. The ZigBee wall router

XR-Z14-CWIP2 from Digi. Permits to implement a ZigBee network at home.

Figure 8. Selected ZigBee wall router

11.5. The Bed presence sensor

NX0310 from Ibernex. It is based on a highly sensitive piezoelectric sensor and permits to determine the presence/absence of a person in bed.

Figure 9. Bed presence sensor from Ibernex.

11.6. Bed sensor hub module

Can be connected to up to two bed presence sensors and sends (through a USB interface) the messages provided by them to the PC.

Figure 10. Bed sensor hub module aspect (manufactured by Ibernex)

11.7. The Fall detector

Contains a triaxial accelerometer and a processing unit. The data sampled from the accelerometer is processed in order to determine a fall situation. It uses a ZigBee wireless link to communicate with the PC at home and a Bluetooth wireless link to communicate with the smartphone when outdoors.

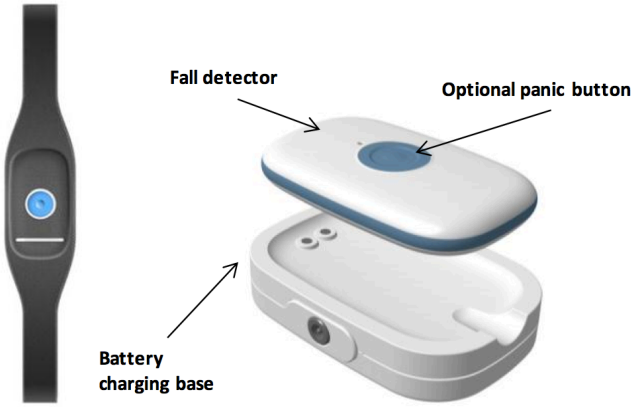


Figure 11. Fall detector view. The Neopren belt is at left.

12. STUDY PROCEDURES

The research procedures performed during the follow-up of the pilots are described in this section. All the participants in the study will be observed for 12 months. Half part of this time they will be using the FATE system (this is called "*intervention period*"), and half part of the time they will be under the standard care (this will be called "*control period*"). These two periods will be separated by 4 months when the participants will not be observed or contacted by the researchers at all. This wash out period is required to clear the carry on effects that the intervention period or the control period may have on participants' behaviour. In each country, half part of the participants will be assigned to start with the intervention period and finish with the control period. Half part of the participants will be assigned to perform the control period first. This "*cross over assignation*" is required to avoid the effects that the order of the periods may have on the outcomes.

The efficacy and safety effects will be measured by comparing the outcomes of the intervention period with the outcomes of the control period. For this purpose in the statistical analysis all the participants will be added in a bigger group of 175 subjects.

Both during the intervention period, and during the control period, the researchers will contact the participant by phone and by the means of scheduled home-visits. The purpose of these contacts is to gather the required data to measure the study outcomes. Additionally, a basal visit will exist before the follow-up periods start. Finally, some of the main outcomes of each period (control and intervention) will be measured in a specific visit at the end of each period (post-control visit and post-intervention visit).

The next sections contain detailed information about the procedures in each specific study period or visit.

The following figure shows the order of the different periods and visits. The shown order is applied to a half of the participants (as it is explained in the text). For the other half of participant the order of periods and visits is just de complementary one.

Figure 12. Study periods and visits schema

12.1. Training of the researchers

A principal investigator (PI) is responsible of the study in each country. This PI may delegate part of the work in as many co-investigators, as he considers necessary. However the Principal Investigator retains overall responsibility for Ethics Committee approval and proper conduct of the study, including obtaining and documenting participant informed consent, compliance with the study protocol, signed Clinical Study Agreement, the collection of all required data, and the training of any additional co-investigator that may be needed during the field work.

The three PI and the co-investigators will receive a 1 day training session, comprising theoretical sessions including guidelines and instructions of all the instruments and questions of the Case Report Form (CRF), and practical sessions with pretended participants who will behave according a number of pre-established situations which will serve an example of the most relevant cases.

12.2. Screening visit.

Participant candidates will be contacted by phone by the PI or a co-investigator who will gather initial data in order to pre-check some inclusion/exclusion criteria: demographic data (age), social data (contact person), functional data (ability to walk) and health data (number of falls, chronic conditions, hospital admissions, implanted electronic devices). Some technical conditions will also be pre-checked in this phone call: GSM coverage, one free wall power plug in the bedroom and 3-4 free wall power plugs distributed through the home.

If the participants fulfil the initial inclusion criteria they will be scheduled for the screening visit. This visit will take place either at the participant's home (or nursing home). This visit will consist in an interview which will last about 30 minutes, and it's main objective is to assess whether the potential participant fulfils the inclusion and exclusion criteria. In this visit the participants will be provided with the "*participant information sheet*" and the informed consent form. The researcher will explain the study purpose, procedures, possible risk and benefits and subject responsibilities to the potential participant. The subjects will be given the opportunity to

evaluate these documents in detail and will be allowed to ask the investigator any question regarding the study.

Firstly, identification data will be validated and the signed and dated informed consent forms will be collected and reviewed. During the interview, the required social and demographic data will be gathered according to the guidelines and the forms included in the CRF (case report forms). The functional status will be assessed by using selected ADL scales included in the CRF (Barthel's index), the fall risk will be evaluated by the self-reported number of falls in the last six months. The cognitive status will be evaluated using the Mini-Mental State Examination. The past medical history will be recorded, including the list of chronic conditions and drugs. Present state of wellness (absence of acute disease) of the participant will be also recorded, as reported by the participants.

Finally, the responsible team defined in the DoW will check the technical requirements for installation of the FATE system. This technical requirements check may be checked in a separate visit, according to the scheduling and availability of the technical researchers in each country.

Screening procedures should be completed prior to the inclusion in the study. Screening procedures must be close, also, to the day of the "*pre-intervention period*" or "*pre-control period*" visits (see below).

12.3. Intervention allocation

All the participants in a given setting will be randomly assigned to receive or to not receive the intervention first. The recruitment coordinator for all the pilots' site will perform the randomization. Each pilot site will send to the coordinator the encoded names of the selected participants, and he will assign each of the participants in each pilot site to receive or not intervention first. Fifty per cent of the participants in each pilot site will be assigned to receive intervention first.

Those participants assigned to receive the intervention will be scheduled for the "**Pre-intervention visit, Implementation of the system user training**" visit (see below). The participants assigned to start with control period will be scheduled for the "**Pre-control period basal**" visits.

12.4. Pre-control period basal visit

This visit can be performed the same day as the "*screening visit*", once the eligibility criteria have been confirmed. The purpose of this visit is to establish the participant's baseline regarding important variables that will be used to estimate the effectiveness of the FATE system.

The PI or a sub-investigator will conduct this visit at the participant's home (it may be a nursing home). The visit will comprise an interview and a physical exam that will last about 45 minutes. During the visit, the researchers will assess fear of falling (FES), balance and gait (Tinetti), functionality (Barthel's, Lawton's, AADL questionnaire, Up & Go test) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF.
The contact person of the participant will be also contacted, and will be asked to complete a structured questionnaire inquiring aspects of the care and/or relationship with the participant, including time devoted to this care or relation ship.

12.5. Control period (unexposed to system)

All the participants will be followed during a period of 6 months while not using the system. During this period, they will be phoned weekly by a researcher, who will gather information about the number of falls and the time to rescue (Structured questionnaire on falls and long lie), the use of sanitary resources (Structured questionnaire on the use of health services), the Professional-participant interaction aspects (including number of interventions prescribed on fall's risk and rehab programs initiated) and the number and severity of possible adverse effects (see definition below).

The participants will also receive a monthly visit, in which a researcher will gather information about the changes in the medical treatment (the addition or discontinuation of drugs that could cause falls) and the level of physical activity (Stanford seven-day physical activity recall questionnaire). During this period it would be convenient for the purposes of the study that the participant keeps a diary on fall events and other adverse effects, which will be checked by the investigators in the monthly visit. The monthly visit will last about 45 minutes.

12.6. Post-control period visit (participant)

The last day of the control period, the researchers will visit the participants. The PI or a sub-investigator will conduct this visit at the participant's home (it may be a nursing home). The purpose of this visit is to track changes from baseline in the variables registered in the pre-control visit. The visit will comprise an interview and a physical exam that will last about 45 minutes. During the visit, the researchers will assess fear of falling (FES), balance and gait (Tinetti), functionality (Barthel, Lawton, AADL, Up & Go) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF. If it is convenient, this visit can be coincident with the last monthly visit of the control period.

The contact person of the participant will be also contacted, and will be asked to complete a structured questionnaire inquiring aspects of the care and/or relationship with the participant, including time devoted to this care or relationship.

12.7. Wash-up period

Between the intervention and control periods, there will be a wash-up period, in which no follow up activities or contacts with the participants will be done. This period will last for 4 months. The purpose of the wash-up period is to leave the participants to return to their basal point, allowing the clearing of the habits acquired by the intervention or the observation. This period is necessary before observing again the participant; otherwise carry-on effects of the first observation could affect the second one.

12.8. Pre-intervention visit, Implementation of the system user training

Before the intervention period starts, the system will be installed at the participants' home. To do so, the required technical personnel will move to participant's home. Once the system is properly deployed and tested, the participant will be trained in using the system. This visit can be performed the same day of the screening visit in the case of the participants that are randomized to receive the intervention first.

All the users of the system will receive clear protocols and users' manual written in their own language. After the training process, the QUEST questionnaire will be used to assess usability and satisfaction, and the structured interview on FATE's usability aspects will be performed.

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 FATE project will provide timely support when necessary at the local places of the pilots.

In the same visit, sanitary personnel or social workers specifically trained to do so, will collect information about fear of falling (FES), balance and gait (Tinetti), functionality (Barthel, Lawton, AADL questionnaire, Up & Go) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF. The purpose of these data collection is to establish the basal set point of these variables before the use of the FATE system.

If training is not successful in the first visit, 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 after two different training sessions will be excluded of the study.

The contact person of the participant will be also contacted, and will be asked to complete a structured questionnaire inquiring aspects of the care and/or relationship with the participant, including time devoted to this care or relationship.

12.9. Intervention period (participant)

The participants will start using the system in their routine live for a period of six months while they are under the research observation.

All the technical incidences, including lost data or erroneous data, will be recorded by the research team, as well as their severity, the actions needed to solve them, and the timing for these actions. Any possible confidentiality loss events will be also registered.

All the data sent by the system will be recorded in a database for later analysis. One day every week the participants will also record in the "technical section" of their "study-diary", every time they switch on or off the system or any of its components, and every time they lie or get up from bed. This recording will help the researchers to estimate the amount of data that is really being transmitted. Additionally, participants will record in the corresponding section of their study-diary all the usability problems they may found at any time.

Similarly to control period, during this period, they will be phoned weekly by a researcher. In this call the researcher will remind the participant to complete the "technical section" of the study-diary the next day, and will gather information about the number of falls in the past week and the time to rescue (Structured questionnaire on falls and long lie), the use of sanitary resources (Structured questionnaire on the use of health services), the Professional-participant interaction aspects (including number of interventions prescribed on fall's risk and rehab programs initiated) and the number and severity of possible adverse effects (see definition below).

During this period the participants will record all fall events and any adverse effects in their "*study-diary*". The participants will also receive a monthly visit, in which a researcher will gather information about the changes in the medical treatment (the addition or discontinuation

of drugs that could cause falls) and the level of physical activity (Stanford seven-day physical activity recall questionnaire). In this monthly visit the researchers will check and record all the sections of the participant's study diary, and will download the data of the activity monitor. The monthly visit will last about 1 hour.

12.10. Intervention period (teleoperators)

During the intervention period, the teleoperators monitoring the participant will act according to the action protocols specifically defined for each pilot site. Each alarm received and each action taken will be stored in a database for later analysis.

On a weekly basis, the teleoperators will fill the usability section of their study diary to register all usability problems detected.

On a daily basis, the teleoperators will fill the technical incidence section of their study diary, in order to report any technical incidence that may occur.

12.11. Post-intervention period visit (participant)

The last day of the intervention period, the researchers will visit the participants. The PI or a sub-investigator will conduct this visit at the participant's home (it may be a nursing home). The visit will comprise an interview and a physical performance exam and, overall, will last about 45 minutes. During the visit, the researchers will assess fear of falling (FES), balance and gait (Tinetti), functionality (Barthel, Lawton, AADL questionnaires, Up & Go) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF.

All the technical stuff deployed in the house will be collected, the QUEST questionnaire and the structured interview on FATE's usability aspects will be performed.

The contact person of the participant will be also contacted, and will be asked to complete a structured questionnaire inquiring aspects of the care and/or relationship with the participant, including time devoted to this care or relation ship.

12.12. Post-intervention period visit (teleoperators and stake holders)

All teleoperators participating in the intervention period will also answer the Quebec User Evaluation of Satisfaction with Assistive Technologies (QUEST) [8]. The usability and technical incidences section of their study diary will also be reviewed, and the study diary collected.

After the intervention period, the teleoperators and the relevant personnel in the different care services in each country will be contact to take part in a structured interview in which their impressions and their satisfaction with the FATE system will be gathered.

12.13. Study visits assessments overview

The following table presents an overview of the different assessments obtained following the visits and actions scheduled in the protocol.

	Screening visit	Pre-control period basal visit	Control period	Post-control period visit	Pre-intervention visit	Intervention period	Post-intervention period visit
Identification data	X						
Demographic data	X						
Social data	X						
Informed consent	X						
Functional assessment	X	X		X	X		X
Fall risk assessment	X						
Mini-Mental State Examination	X						
Medical assessment	X						
Technical conditions check	X						
Fear of falling		X		X	X		X
Balance and gait assessment		X		X	X		X
Quality of life		X		X	X		X
Questionnaire to the contact person		X		X	X		X
Falls diary			X			X	
Structured questionnaire on falls and long lie			X			X	
Physical activity questionnaire			X			X	
Structured questionnaire on health services			X			X	
Structured questionnaire on rehab prescriptions			X			X	
Recording of adverse effects			X			X	
Drug regime changes			X			X	
Implementation					X		
Training					X		
Usability and satisfaction assessments					X		X
System performance measurements						X	
Usability diary						X	
Questionnaire to teleoperator						X	X
Interview stakeholders							X

Table 1. Study assessments overview

13. STUDY COMPLETION PROCEDURES

13.1. Participant completion of study

Subjects are considered to have completed the study if they have completed the follow-up period, including the corresponding intervention and control periods. All subjects enrolled in the pilots (including those withdrawn from the pilots) shall be accounted for and documented.

13.2. Discontinuation of the intervention

Unless otherwise indicated, a subject must permanently discontinue the use of the system for any of the following reasons:

- The subject desires to discontinue the intervention under this protocol.
- The subject experiences a medical emergency that necessitates permanent discontinuation of intervention.

The reason(s) for discontinuation of the intervention must be recorded in the subject's case report form (CRF). Subjects who discontinue the intervention may remain in the study and continue protocol-required test and assessments.

13.3. Participant withdrawal

Subjects may be withdrawn from the study at the discretion of the researcher if one of the following occurs:

- The subject voluntarily discontinues his or her participation in the study.
- Continuation of the intervention would jeopardize the participant's health and/or welfare.
- There is a concurrent illness (unrelated to the intervention) that prevents the subject from complying with follow-up evaluations.
- The subject is unwilling or unable to comply with the protocol.

The reasons for the subject's withdrawal from the study must be recorded in the subject's CRF. All withdrawn subjects will be followed for any adverse events for the entire period of the study.

The sponsor or its designee must be notified of a participant termination immediately.

13.4. Participant Exit

Participant exit forms must be completed for all subjects who either complete the study, discontinue participating in the study, are considered lost to follow-up, or are withdrawn from the study. Before a subject is considered "lost to follow-up", there must be at least two documented attempts to contact the subject.

14. STATISTICAL ANALYSIS

14.1. Baseline and demographic characteristics of the participants

This part of the analysis tries to characterize the subjects' population. The basal data will be examined by the means of descriptive statistics: n, mean and standard deviation, for normal variables, median and inter-quartile range for non-normal variables, and frequencies for categorical variables.

14.2. System's performance variables analysis

Variables regarding stability, transmission reliability and system's security will be descriptively analysed by reporting frequencies of the different related events.

14.3. System's validity analysis

The sensitivity, specificity, positive predictive value and negative predictive value will be estimated in order to evaluate the validity of the system for fall detection. This will be mainly done by comparing the falls detected by the system against the gold standard (falls reported by researchers in the weekly interview or by users in their falls diary).

14.4. System's effectiveness analysis

In order to estimate the efficiency of the system the different health outcomes will be compared between the intervention period and the control period. For some health outcomes their different incidence during the intervention and control period will be compared (ex. number of falls, contacts with GP…). Those results measured by specific instruments (ex. Barthel's index, Falls Efficacy Scale…) will be analysed by comparing means, medians or other central estimators, as appropriate, between the control and intervention periods.

14.5. System's safety analysis

The safety analysis will be performed by comparing the incidence of adverse events between periods of intervention and control, and the number of participants withdrawn or leaving the study due to adverse effects in both periods. The analysis will be stratified by the severity of adverse effects.

14.6. Usability and user satisfaction analysis

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.

14.7. To estimate system's efficiency

System efficiency will be studied from the safety and effectiveness data, which will be completed with cost analysis available in the literature, and the cost provided by the companies that manufacture the system.

14.8. To measure in what extent the scalability aspect has been achieved.

Scalability aspects will be evaluated and analysed from quantitative data on traffic analysis (data and communication).

14.9. To gather users and stakeholders opinions on the system and its utility. To gather data for creating or evaluating a business plan.

Users and stakeholder opinions will be collected along the pilot using specifically designed questionnaires. System utility would be evaluated from qualitative discussions after and during the piloting experience.

15. ADVERSE EVENTS

15.1. Definition

An **adverse event (AE)** is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.

Inter-current illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- Results in study withdrawal
- Is associated with a serious adverse event
- Is associated with clinical signs or symptoms
- Leads to additional treatment or to further diagnostic tests
- Is considered by the investigator to be of clinical significance

A **serious adverse event (SAE)** is any adverse event that:

- Led to death;
- Resulted in a life-threatening illness or injury;
- Resulted in a permanent impairment of a body structure or a body function;
- Required in-participant hospitalization or prolongation of existing hospitalization;
- Resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function;
- An important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-participant hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

The condition, hospitalization, prolonged hospitalization, or surgery are not reported as an adverse event in the following circumstances:

- Hospitalization or prolonged hospitalization for diagnostic or elective surgical procedures for a pre-existing condition. Surgery should not be reported as an outcome of an adverse event if the purpose of the surgery was elective or diagnostic and the outcome was uneventful.
- Hospitalization or prolonged hospitalization for therapy of the target disease of the study (falls), unless it is a worsening or increase in frequency of hospital admissions as judged by the clinical investigator.

A **Serious pre-intervention event** is any event that meets the criteria for Serious Adverse Event and occurs after the subject signs the Informed Consent Form (ICF), but before administration of study intervention.

An **adverse device effect** (ADE) is any adverse event related to the use of an investigational medical device. This definition includes any event resulting from insufficiencies or inadequacies in the instructions for use or the deployment of the device, or any event that is a result of a user error, or from intentional misuse of the investigational device.

A **Serious Adverse Device Effect** (SADE) is an adverse device effect that has resulted in any of the consequences characteristics of a serious adverse event or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune.

An **Unanticipated Serious Adverse Device Effect** (USADE) is a serious adverse device effect, which by its nature, incidence, severity or outcome has not been identified, in the current version of the risk analysis report

Anticipated Adverse Events:

- Skin reactions to the belt that fix the sensor to the body.

15.2. Adverse Events Classification

The severity of adverse events will be rated as follows:

1. Mild (Grade 1): An AE which is transient or mild in nature, which does not limit the subject's activity, and which does not require medical intervention
2. Moderate (Grade 2): An AE which has mild-moderate impact on the subject's activity or requires minimal medical intervention or monitoring
3. Severe (Grade 3): An AE which has marked impact on the subject's activity or requires medical care
4. Serious – life threatening (Grade 4): A serious adverse event (SAE) is any adverse event that is fatal or life threatening, results in persistent or significant disability, requires intervention to prevent permanent impairment / damage, or an event that results, admission to or prolongation of hospitalization.
5. Grade 5 - Death

The relationship of the AE and SAE to the treatments or procedures is defined as follows:

1. Unrelated: Any event that does not follow a reasonable temporal sequence from administration of study intervention AND that is likely to have been produced by the subject's clinical state or other modes of therapy administered to the subject.
2. Unlikely: Any event that does not follow a reasonable temporal sequence from administration of study intervention OR that is likely to have been produced by the subject's clinical state or other modes of therapy administered to the subject.
3. Possibly: Any reaction that follows a reasonable temporal sequence from administration of study treatment OR that follows a known response pattern to the suspected drug/intervention AND that could not be reasonably explained by the known characteristics of the subject's clinical state or other modes of therapy administered to the subject.
4. Related: Any reaction that follows a reasonable temporal sequence from administration of study treatment/intervention AND that follows a known response pattern to the suspected drug/intervention AND that recurs with re-challenge, AND/OR is improved by stopping the drug/intervention or reducing the dose.

15.3. Adverse Events Reporting

Throughout the course of the study, every effort will be made to capture and evaluate adverse events or untoward findings. If adverse events occur, the first concern is for the safety and welfare of the subject. Appropriate medical intervention will be made. Any adverse events or complications observed by the Investigator or reported by the subject, whether or not ascribed to the FATE system, are to be recorded in the appropriate section of the subject's CRF and on the "Adverse Event" CRF. The relatedness of the adverse event to the FATE system will be assessed by the investigator and documented on the Case Report Forms. The Investigator must submit the filled CRFs to the Sponsor for review, including the description of the event, date of onset, an evaluation of the relatedness of the adverse event to the FATE system, medical assessment for seriousness, actions taken and whether study intervention was discontinued, and event resolution.

Serious adverse events that are still ongoing at the end of the study period must be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study treatment or study participation should be recorded and reported immediately.

A pre-existing condition, which is a condition that is present at the beginning of the study should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

A clinical laboratory abnormality should be documented as an adverse event if any one of the following conditions is met:

- The laboratory abnormality is not otherwise refuted by a repeat test to confirm the abnormality
- The abnormality suggests a disease and/or organ toxicity
- The abnormality is of a degree that requires active management; e.g. change of dose, discontinuation of the drug, more frequent follow-up assessments, further diagnostic investigation, etc.

The sponsor is responsible for the classification of adverse events and on-going safety evaluation of the clinical investigation and shall:

- Review the investigator's assessment of all adverse events and determine and document in writing their seriousness and relationship to the investigational device; in case of disagreement between the sponsor and the principal investigator(s), the sponsor shall communicate both opinions to the EC and the national regulatory authorities, if required
- Review all device deficiencies and determine and document in writing whether they could have led to a serious adverse device effect; in case of disagreement between the sponsor and the principal investigator(s), the sponsor shall communicate both opinions to the EC and the national regulatory authorities, if required
- Report or ensure the reporting, to the EC by the principal investigator(s), of all serious adverse events and device deficiencies that could have led to a serious adverse device effect, if required by national regulations or by the EC. The investigator must inform the sponsor and the local EC about any serious adverse effects and serious adverse device effects as soon as becoming aware of the occurrence by Fax/Telephone.
- Report to regulatory authorities, within the required time period, all serious adverse events and device deficiencies that could have led to a serious adverse device effect, if required by national regulations
- Inform all principal investigators in writing of all the serious adverse events at all investigation sites that have been reported to the sponsor, and ensure that they are reported to their EC, if required by national regulations; this information shall be sent to all the principal investigators within a time frame established based on the perceived risk as defined in the risk analysis report
- Ensure that the EC and the regulatory authorities are informed of significant new information about the clinical investigation
- In case of serious adverse device effects and device deficiencies that could have led to serious adverse device effects, determine whether the risk analysis needs to be updated and assess whether corrective or preventive action is required.

15.4. Device Deficiencies

A Device Deficiency is defined as inadequacy of the device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies may include malfunctions, user errors and inadequate labelling. Examples of deficiencies with the FATE system may include:

- Missing product components;
- Missing or illegible product associated labelling;
- Device components which appear malformed or disfigured;
- Software bugs

All device malfunctions will be recorded in the appropriate field on the participant CRFs.

15.5. Procedures for handling special situations.

Medical emergency: In a medical emergency requiring immediate attention, study site staff will apply appropriate medical intervention, according to current standards of care, and contact the sponsor.

16. Investigation Administration

The investigation will be conducted in compliance with ICH Guideline for Good Clinical Practice, relevant FDA guidelines, ISO 14155:2011(E), and any relevant European directives.

16.1. Ethical Committee (EC) Information

This protocol and the informed consent (IC) form must be reviewed and approved by the appropriate EC where the study is to be conducted before enrolment of participants.

Changes to the protocol that may increase the risk or present new risks to the participant, or may adversely affect the validity of the trial, must be approved in writing by the sponsor and the EC before the change in implemented

16.2. EC approval Letter

EC approval to participate in this trial is required from each institution participating in this investigation. Prior to participant enrolment, a signed copy of the EC approval letter addressed to the investigator must be submitted to the sponsor certifying study approval. Investigators are responsible for submitting and obtaining review of the study by their EC according to the national rules and regulations.

16.3. Responsibilities of Sponsor and Investigator

16.3.1. Principal Responsibilities of Sponsor

Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that EC review and approval are obtained. Additionally, the sponsor is responsible in ensuring that any reviewing EC, and relevant competent authorities are promptly informed of significant new information about the investigation. The sponsor is responsible to comply with applicable governmental regulations.

16.3.2. Principal Responsibilities of Clinical Investigator

The role of the principal investigator is to implement and manage the day-to-day conduct of the clinical investigation as well as ensure data integrity and the rights, safety and well being of the subjects involved in the clinical investigation.

Each Investigator agrees to comply with all applicable governmental regulations and the requirements of this study. Investigators who do not comply with the protocol, or conditions included in approvals granted by the reviewing committee, will have their participation in the study terminated.

16.4. Responsibilities and Duties of Monitor

16.4.1. General

The sponsor will conduct investigational site monitoring to ensure that all investigators are in compliance with the protocol, regulatory requirements and the Investigator's agreement.

The sponsor will review significant new information, including unanticipated adverse events and ensure that such information is provided to the study investigators and all reviewing EC

16.4.2. Study Monitor Responsibilities

Monitoring functions shall be performed in compliance with Good Clinical Practices, ISO 14155:2011(E).

The major function of the clinical monitor is to observe and assess the quality of the clinical study. Thus, periodic visits are intended to assess investigator's adherence to the protocol, maintenance of records and reports, and review of source documents for accuracy, completeness, and legibility. At the completion of the study, the monitor may be required to make a final on-site visit to assure that all study data has been properly completed and that the investigational product has been returned to the sponsor.

Reports of on-site visits shall be made by the monitor and should include, as applicable, resolution of concerns, completion of appropriate follow-up activities, completion of assigned tasks, and corrective actions.

The monitor is then responsible to verify and report:

- That compliance with the clinical investigation plan is maintained and that any deviation from the clinical investigation plan is reported;
- That the device is being used according to the clinical investigation plan. If modifications are required either to the device or its method of use or to the clinical investigation plan, this need has to be reported to the sponsor;
- That the investigator(s) has (have) and continue(s) to have staff and facilities to conduct the clinical investigation safely and effectively;
- That the investigator(s) has (have) and continue(s) to have access to an adequate number of eligible subjects and devices
- That signed and dated informed consent forms have been obtained from each subject at the time of enrolment and before any study-related procedures are undertaken;
- That the data in the case report forms are complete, are recorded in a timely manner and are consistent with the source data;
- That the procedures for recording and reporting adverse events and adverse device effects to the sponsor are followed;
- That there is a process in place for device accountability and traceability and that it is maintained;
- That the maintenance and calibration of the equipment relevant for the assessment of the clinical investigation is performed and documented.

At the completion of the study, the monitor may be required to make a final on-site visit to assure that all study data has been properly completed and that the investigational product has been returned to the sponsor.

Reports of on-site visits shall be made by the monitor and should include, as applicable, description of concerns, completion of appropriate follow-up activities, completion of assigned tasks, and corrective actions.

16.5. Data Monitoring and Quality Control

A Case Report Form (CRF) booklet for each subject enrolled in the study will be used. CRFs must be fully completed for each participant and signed by the investigator in blue or black ink and monitored as per standard requirement. The sponsor will train the site personnel to correctly record the clinical data into the CRF. Specific CRF will be used for usability evaluation questionnaire. Each study follow-up will be completed and signed by the investigator in blue or black ink. Drawing a single line through the incorrect entry, entering the correct information, and initialling and dating the change, will make any corrections. Data entry boxes or spaces should not be left blank, but instead should indicate: NA for not applicable, ND for not done or "-"for missing or not available data. All CRFs will be tracked and missing or unclear data will be requested as necessary through the trial. The originally signed CRFs will be delivered to the sponsor after source verification.

16.6. Participant Confidentiality

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.

16.7. Participant Informed Consent Form

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 participant and the local investigator will be obtained from each participant. 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 participant.

16.8. Investigator/Study Discontinuation

Any investigator will be removed from the study if he/she demonstrates a pattern of non-adherence to the study protocol and/or unethical behaviour.

16.9. Study Discontinuation

The study may be discontinued if at any time, in the opinion of the hospital ethics committee and the principle investigator, the study represents an unreasonable medical risk to participants, or the sponsor decided to terminate the study due to company considerations.

17. Protocol Modifications

17.1. Protocol deviations

The instructions and procedures specified in this protocol require diligent attention to their execution. Except for an emergency situation in which proper care for the protection, safety and wellbeing of the study subject requires alternative treatment, the study shall be conducted

exactly as described in the approved protocol. No alterations or changes to this protocol will be permitted. However, should there be question or consideration of deviation from the protocol, clarification must be sought from the sponsor's monitor. Any subject treated in a manner that deviates from the protocol, or who is admitted into the study but is not qualified according to the protocol, may be ineligible for analysis and thereby compromises the study. The investigator and research team must comply with all applicable international and national laws.

17.2. Protocol amendments

The investigators, or study personnel, without first obtaining review and the agreement of the study coordinator and the sponsor cannot amend the protocol. Medically significant amendments to the protocol (e.g., affecting the rights, safety, or wellbeing of the human subjects involved in the investigation, the scientific soundness of the investigational plan, the validity of data or information resulting from the completion of an approved protocol, or the relationship of the likely participant risk/ benefit relied upon to approve a protocol or if there are otherwise significant inclusion of new categories of participants, etc.) may not be instituted prior to approval by the relevant Ethics Committee and regulatory approval by relevant Competent Authorities

ANNEX 1. FATE equipment list for senior living facilities.

Gema Active Business Solutions provides a real time locating, identifying and monitoring RFID (Radio Frequency Identification) technology-based solution, destined to senior living facilities that allows the protection and supervision of residents. The trials of FATE with 50 users that living in residence in Spain will take place in facilities using this solution. Integration between locating and identifying solution and fall detection and bed presence will be needed. In this case, the Tag (wireless input OEM module) and the fall detector will be integrated in one device, as the bed sensor too (bed sensor + Tag).

In the following figure an overview of the architecture can be seen:

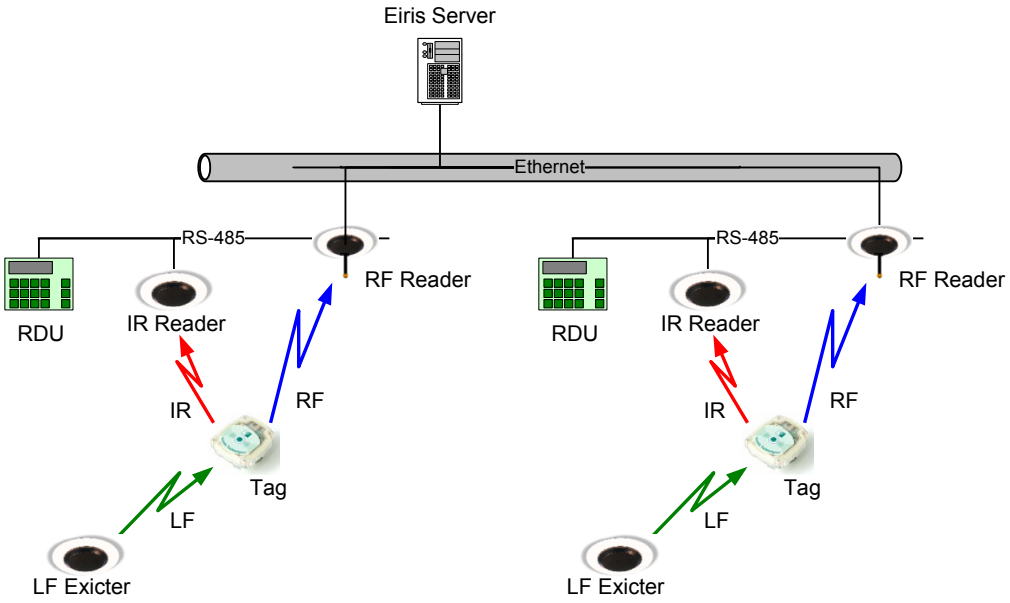


Figure A1.1 Architecture overview.

The FATE infraestructure at residences is composed by the following elements:

- Eiris Server (locating and identifying software platform)
- Local area network
- Readers RF, LF Exciter and IR
- Tags + Fall detector units integrated in one device
- Tags + Bed sensor units integrated in one device
- EDP (ElPas Display Panel) ~ RDU (Remote Display Unit)
- Infraesterucutre accessories (Junction Box, mounting bracket , etc..)

In the following, some basic specification of these parts is included.

Elpas
Active RFID/RTLS Solutions

RF IP Ceiling Reader

Description

The Elpas RF IP Ceiling Reader is a supervised; 433MHz fixed receiving device. The reader is designed to detect, and relay real-time 'Location' and 'State' data from Elpas Active RFID Asset, Personnel or Infant Protection Tags to host applications.

The RF IP Ceiling Reader supports standard IT network communications and is easily integrated onto wired or wireless Ethernet/Wi-Fi networks to enable indoor, facility-wide monitoring and tracking of assets or personnel in real-time.

Architecturally attractive, the RF IP Ceiling Reader is easily surface mounted onto solid ceilings or flush mounted into dropped (false) ceilings. The reader supports large tag populations at read-distances up to 20m/65ft (360° coverage area) in open office environments and is remotely configurable for customized applications. On-board I/O ports enable the monitoring of one general purpose analogue input and control of two open-collector digital switched outputs.

The RF IP Ceiling Reader supports XML messaging technology for integration with external control and monitoring applications plus full-duplex data transmission with up to 15 Elpas RS-485 BUS devices.

Elpas RF IP Ceiling Reader

Elpas RF IP Ceiling Reader – Confidential Technical and Product Specifications

Operational Specifications	
Operating Frequency	432.92 MHz (868 MHz upon special request)
Ethernet	10/100Base –TX (auto-sensing)
Ethernet Specification	Version 2.0 / IEEE 802.3, Ethernet II frame type, UDP protocol
RS-485 BUS	230Kbit/sec
Read-Range (Note 1)	Installation grid: 20m/65ft radius
Sensitivity	-102dbm
Tag Density	Up to 125 tag messages/second
Message Length	4-31 byte messages (encapsulated for messages > 4 bytes)
Buzzer Indicator	Upon power-up: Remotely configurable… ….Device Malfunction: Beeps continuously
Green LED Indicator	Upon power-up: Lites continuously
Red LED Indicator	Corrupted firmware- lights continously Unregistered in EIRIS: Toggles on/off every second Tag/Badge Detection: Flashes once per message
Service Pin	Generates service message
Encoding	Factory programmed ID
Input/Outputs	1 dry contact analogue input 2 open collector digital outputs (up to 100mA)
Power Requirements	16-28Vdc, 80mA at 24Vdc=2W
General Specifications	
Mounting	Ceiling flush mount
Construction	White polycarbonate plastic
Dimensions	17cm x 4 cm (6.6 inches x 1.6 inches)
Weight	200grams/7.054 ounces approximate
Tamper Protection	Open 'State' spring-loaded switch button
Device Interfaces	RF antenna: Female RP SMA connector Ethernet: Female RJ-45 (8P8C) connector RS-485 Bus & Power: Female RJ-11 (4P4C) or Four–position removable terminal block Analogue Input: Two–position fixed terminal block Digital Outputs: Three–position fixed terminal block
Operating Environment	Temp: -10°C to 70°C (14°F to 159°F); Humidity: 20% to 80% non-condensing
Storage Temperature	-40° to 70°C (-40°to 159°F)
Remote Configuration and Supervision	EIRIS 4.6.3 (or higher) software
Compliance Standards	FCC: FCC PART 15, Sub-part B, Class B CE: EN60950-1, CAN/CSA-CEI/ICE CISPR 22 IC: ICES-003
Warranty	1 year limited warranty

Figure A1.2 Basic reader RF IP specification.

Elpas
Active RFID/RTLS Solutions

LF Exciter

Description

The Elpas Low Frequency (LF) Exciter from Visonic Technologies is a supervised, short-range, UHF emitter that adds pin-point detection functionality to any Elpas safety, security or monitoring installation.

The LF Exciter is engineered to emit spherical, low-power electromagnetic fields (125 KHz) of up to 3 m (10 ft) in radius. These harmless LF fields are user-adjustable, so that they can be tuned to precisely cover most indoor doorways or entrance/exit areas. So, whenever an individual or asset bearing an Elpas active RFID tag enters the electromagnetic field generated by the exciter, the mobile tag is prompted to transmit its pre-programmed data messages (including the exciter's Neuron ID). The messages are instantly detected by the Elpas RF reader infrastructure and are locally processed and/or relayed over the LonTalk network to the EIRIS server machine in support of the configured Elpas application.

Elpas LF Exciter

Elpas LF Exciter – Confidential Technical and Product Specifications

LF Specifications	
Technology	Low frequency electromagnetic field (125 KHz)
Effective Range	Up to 3 m (10 ft) radius (spherical field)
Transmission Rate	Continuous bursts of LF transmissions (each about 12 ms in duration)
Output and Format	3-byte messages (preamble, exciter ID and CRC)
Output Power	Less than 60 dbμv at 30 m (100 ft); adjustable, using the onboard trim control potentiometer
Output Bit Rate	2,000 bit per second
RF Specifications	
Technology	UHF RF (433.92 MHz)
Effective Range	20 m (65.5 ft) radius (360° coverage area)
Transmission Rate	1 RF transmission (about 2 ms in duration), 10 seconds apart
Electrical Specifications	
Status Inidcators	Power On: Red LED blinks 5 times upon power on, then lights constantly Invalid ID Code: Red LED blinks continuously; buzzer beeps repetitively
ID Address	Set by an onboard, 8-position DIP switch
Power Requirements	24 V DC nominal ± 30%; 200 mA
Power Consumption	Approximately 2W; power consumption is a function of address (according to the DIP switch settings, where FF is the maximum and 00 is the minimum)
General Specifications	
Construction	Polycarbonate plastic
Dimensions (H x W x D)	17 x 4 cm (6.6 x 1.6 inches)
Weight	Approximately 200 grams (7.054 ounces)
Device Interfaces	RJ-11 (6P6C) power source connector RJ-45 (8P8C) master-slave connector
Operating Environment	Temperature: -10°C to 70°C (14°F to 159°F) Humidity: 20% to 80%, non-condensing
Remote Management	EIRIS 4.5 (or higher) enterprise software
Compliance with Standards	FCC: FCC ID: 04X5-RLE00125, FCC PART 15, Sub-part B, Class B, Sub-part C; CE: EN300220-1, EN300220-2, EN300330-1, EN300330-2, EN301489-1, EN301489-3, EN60601-1-2, CISPR 11, EN60950-1, IEC60601-1, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-6
Warranty	1-year limited warranty (excluding battery)

Figure A1.3 Basic reader LF specification

Elpas
Active RFID/RTLS Solutions

IR BUS Ceiling Reader

Description

The Elpas High-Resolution IR BUS Ceiling Reader from Visonic Technologies is a supervised, fixed infrared locating device. The reader is designed to detect and relay sub-room 'Location' and 'State' data in real-time from Elpas Active RFID IR-Enabled Asset, Personnel or Infant Protection Tags to host applications.

The reader can be easily integrated anywhere onto wired or wireless Ethernet/Wi-Fi networks (using an Elpas RF IP Reader as a RS-485 BUS master) to enable indoor facility-wide sub-room monitoring and tracking of assets or personnel in real-time.

Architecturally attractive, the reader is easily surface mounted onto solid ceilings or flush mounted into dropped (false) ceilings. The Elpas High-Resolution IR BUS Ceiling Reader supports large tag populations at read-distances up to 15m/50ft (360° coverage) and is remotely configurable for customized applications. Onboard I/O ports enable the monitoring of one general purpose analog input and control of one open-collector digital switched output.

The Elpas High-Resolution IR BUS Ceiling Reader also supports XML messaging technology (via the Elpas RF IP Reader) for integration with external systems plus full-duplex data transmission with up to 15 Elpas RS-485 BUS devices.

Elpas IR BUS Ceiling Reader

Elpas IR BUS Ceiling Reader – Confidential Technical and Product Specifications

Operational Specifications	
Operating Frequency	455KHz
Read Range (Note 1)	Installation grid: 15 m / 50 ft radius
Tag Density	Up to 50 tag messages per second
Message Lenght	4–31 byte message (encapsulated for messages > 4 bytes)
Buzzer Indicator	Upon power-up: beeps once Device malfunction: beeps continuously
Visual Indicators	Corrupted firmware: red LED lights continuously Unregistered in EIRIS: red LED blinks every second Tag/Badge detection: flashes once per message
Service Pin	Generates service message
Encoding	Factory-programmed ID
RS-485 BUS	230Kbit/sec
Input / Output	1 analog input, 1 open collector digital outputs (up to 100 mA)
Power Requirements	16–28 Vdc/50mA
General Specifications	
Mounting	Surface-mounted on solid walls and ceilings, flush-mounted into dropped (false) ceilings
Construction	Black poly carbonate plastic
Dimensions (H x W x D)	17 x 4 cm (6.6 x 1.6 inches)
Weight	Approximately 200 grams / 7.0 ounces
Tamper Protection	Open 'State' spring loaded switch button
Device Interfaces	RS-485 Bus & Power: Female RJ-11 (4P4C) or Four–position removable terminal block One Analog Input: Two-position fixed terminal block One Digital Output: Two-position fixed terminal block
Operating Environment	Temp: -10°C to 70°C (14°F to 159°F); Humidity: 20% to 80% non-condensing
Storage Temperature	-40° to 70°C (-40°to 159°F)
Remote Management	EIRIS 4.6.3 (or higher) software
Compliance Standards	CE: EN300220-1, EN300220-2, EN60950-1, ICES-003, CAN/CSA-CEI/ICE CISPR 22 FCC: FCC PART 15, Sub-part B, Class B FCC ID: O4X5-IRB0088 IC: 1467G IRB00880
Warranty	1-year limited warranty

Figure A1.4 Basic reader IR specification

Fall detection in real time

When a fall is detected in any place of the residence, a transmission from Tag is generated in real time and transmitted to the facility staff members (DECT phones, Display panels and PC), indicating the person fallen and its location. The same process will happen when, under the conditions configured, an alert must to be generated when an elder leaves the bed, since the bed presence sensor is integrated too with the locating and identifying solution.

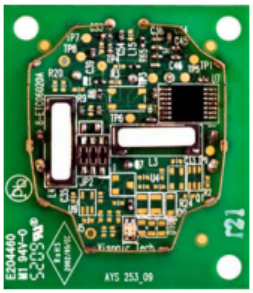
Elpas
Active RFID/RTLS Solutions

Wireless Input OEM Module

Description

The Elpas Wireless Input Module is an embedded PCB board OEM connectivity solution. The module provides a 433MHz, wireless interface to the Elpas RTLS fixed network infrastructure for the remote monitoring of single or multi-level staff/patient/resident call points, pull switches or any other ancillary facility monitoring points.

The module monitors and reports on 'State' changes of up to three analog inputs in real-time to a host Elpas RTLS application or to other third-party staff and patient care monitoring solutions. The LF-enabled version (P/N 5-ETC90010-1) also includes a low frequency LF receiver (125KHz) that enables real-time location detection that can be used to protect against the unauthorized removal of the call point from the area being monitored.



Elpas Wireless Input OEM Module
(actual PCB may vary in appearance)

Specifications	
Radio Technology	RF (433.92 MHz) and LF (125KHz)
Transmission Range	20 meters / 65 Ft (360° coverage area)
Transmission Rate	Every 60 seconds
LF Sampling	Every 150ms
Device Inputs/Outputs	**Inputs:** 3 analog contacts....**Output:** ACK signal
Power Requirements	3.3VDC +/-30%; 285mAh
Power Sources	On-board lithium battery, (type CR2430 - supplied) or via host call/monitoring point
Battery Life	Approximately 5 years
Module ID	Unique factory programmed ID
Construction	PCB board (no enclosure)
Dimensions (H x W x D)	39 x 35 x 10 mm / 1.5 x 1.4 x 0.64 inches
Weight	9 grams/ 0.75 ounces (with battery)
Device Interface	6-pin low profile connector for: input power, 3 dry contact inputs/ ACK output signal
Operating Environment	**Temp:** -10°C to 70°C (14°F to 159°F); **Humidity:** 20% to 80% non-condensing
Compliance Stanards	**FCC:** GSA-ETC00433 .....**IC:** 1467G-ETC00433.....**CE:** EN 300 220-1, EN 300 220-2, EN301 489-1, EN301 489-3, EN 60601-1-2, CISPR 11: 2004, IEC 61000-4-2, IEC 61000-4-3
Warranty	1 year limited warranty (excluding battery)

Specifications - Subject to change without notice

Ordering Information

Part Number	Description
5-ETC90010-1	Wireless Input OEM, RF/LF, 433Mhz, (Pack of 10)
5-ETC90010-2	Wireless Input OEM, RF, 433Mhz, (Pack of 10)
5-BC012430	3V/270mAh Lithium Battery, CR2430 (25 pcs)

Figure A1.5 Wireless input OEM module overview

The described alarm conditions are obtained from the correct connection between the standard wireless input OEM module and the fall detector or the bed presence sensor. Two different sub-systems are seen:

- Tags (Wireless Input OEM Module) + Fall detector units integrated in one device
- Tags (Wireless Input OEM Module) + Bed presence sensor units integrated in one device

The complementary fall detector and bed presence sensor sub-systems are described in the following text.

- **Fall detector:** Contains a triaxial accelerometer and a processing unit. The data sampled from the accelerometer is processed in order to determine a fall situation.

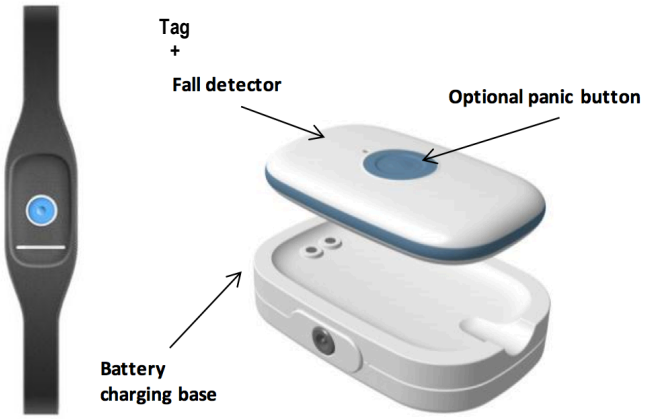


Figure A1.6 Fall detector sub-system overview

- **Bed presence sensor:** NX0310 from Ibernex. It is based on a highly sensitive piezoelectric sensor and permits to determine the presence/absence of a person in bed. Will be integrated with the tag and encapsulated into a box.

Figure A1.7 Ibernex bed presence sensor aspect

Elpas
Active RFID/RTLS Solutions

Elpas Display Panel

Description

The Elpas Display Panel (EDP) is a wall mountable, remote management panel that enables users to view and clear individual system alerts and to manage the status of specific Elpas Active RFID tags without the need to access a host RTLS client station.

The EDP contains a four-line, twenty-character LCD for displaying real-time tag and alert status information and a keypad for managing open alerts or tag status. The device has an audible buzzer for indicating the receipt of a new alert or of device malfunction and supports one analog device input and the control of one open-collector digital output.

The BUS Version of the EDP (P/N 5-EDP00485) is powered and communicates via RS-485 while the IP Version of the device (P/N 5-EDP00485-1) supports Ethernet network communications for relaying data to and from a host RTLS application.

The Elpas Display Panel is remote configurable using Eiris Tracking & Management or ELC Programmer Software and supports data transmission with up to fifteen other Elpas BUS devices such as RF or IR Readers, I/O Modules, LF Exciters and/or Proximity Readers.

EDP – Closed Panel View

EDP – Open Panel View

Elpas Display Panel (EDP) – Confidential Technical and Product Specifications

Specifications	
Display	4 line-20 character illuminated LCD
Ethernet – IP Version	10 Base –TX (auto-sensing) / UDP protocol
RS-485 BUS	230Kbit/sec
Green LED Indicator	Lights continuously when powered
Red LED Indicator	**Corrupted Firmware:** Lights continuously **Unregistered in Software:** Toggles on/off every second
Audible Indicator	**Power-Up:** User configurable…….**Device Malfunction:** Beeps continuously **Incoming Alerts:** User configurable
Power Requirements	12–28 VDC **BUS Version**: 60mA……**IP Version:** 100mA
Construction	White polycarbonate plastic
Dimensions (H x W x D)	11 x 16 x 2.5 cm (4.3 x 6.3 x 1.0 inches)
Weight	260 grams (9.0 ounces)
Keypad	Slim-line landscape keypad
Device Interfaces – IP Version	**Ethernet:** Female RJ-45 (8P8C) connector **Digital Input/Output:** Three-Position terminal block **Power:** Two-Position terminal block
Device Interfaces – BUS Version	**RS-485 Data Bus & Power:** 2 Female RJ-11 (6P6C) connectors **Digital Input/Output:** Three-Position terminal block **Power:** Two-Position terminal block
Encoding	Factory programmed ID
Input/Output	1 analog input 1 open collector digital output (up to 100mA)
Operating Environment	**Temperature:** -10°C to 70°C (14°F to 159°F) **Humidity:** 20% to 80%, non-condensing
Storage Temperature	-40° to 70°C (-40°to 159°F)
Remote Management	ELC Programmer Software (V2.0 or higher)….EIRIS 4.7 (or higher) Enterprise Software
Compliance Standards	CE, FCC, IC Compliant
Warranty	1-year limited warranty

Figure A1.8 EDP display panel basic specifications

Elpas
Active RFID/RTLS Solutions

RS-485 Junction Box

Description

The Elpas RS-485 Junction Box is a multi-drop, solid state fixed network accessory that provides installers with a convenient power/data interface for linking Elpas RS-485 BUS devices together.

Each box contains four female RJ-11 (6P6C) modular jacks that support Elpas Network Drop Cables, for the easy connection of Elpas BUS devices. The device has two loop-through 8 pin 110 punch-down block connectors to enable multiple RS-485 Junction Boxes to be connected in a daisy-chain wiring configuration via CAT-5 cabling.

For powering the RS-485 BUS, the junction box contains a two–position removable terminal block for connecting to an Elpas PS60 Power Supply or to other compatible third-party16-28VDC/2.5A power sources. The junction box also has a two–position terminal block for BUS end of-the-line termination and a green LED Power ON status indicator.

Constructed of white polycarbonate plastic, the RS-485 Junction Box can be surface mounted onto solid walls and ceilings or easily located above dropped (false) ceilings.

Elpas RS-485 Junction Box

Elpas RS-485 Junction Box – Confidential Technical and Product Specifications

Specifications	
Total Pass Through Current	2.5 Amps
RS-485 BUS	230Kbit/sec
RS-485 Backbone Interface	Two eight–pin 110 punch down blocks
RS-485 Bus Device Interfaces	Four RJ-11 (6P6C) female network drop connectors (for RS-485 data & 16-28 VDC)
Power Interface	Two–position removable terminal block (for 16-28 VDC)
End of-the-Line Termination	Two–position terminal block
Green LED Indicator	Upon power-up, lights continuously
Construction	White polycarbonate plastic
Dimensions (H x W x D)	110 x 63 x 26mm (4.3 x 2.5 x 1.0 inches)
Weight	70 grams/ 2.5 ounces
Operating Environment	**Temp**: -10°C to 70°C (14°F to 159°F) **Humidity:** 20% to 80% non-condensing
Warranty	One year limited warranty

Figure A1.9 RS-485 Junction box basic specification

Elpas
Active RFID Solutions

Technical Specifications
Reader Mounting Bracket

Description

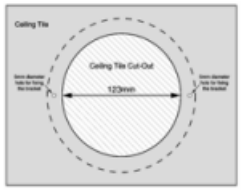
The Reader Mounting Bracket is used to flush mount Elpas LF Exciters or Location Readers in suspended ceiling tiles.

The bracket is constructed of coated steel and has a 15mm/0.59inch center hole to allow cables to pass through. The bracket also contains two 4mm/0.16inch diameter threaded holes; (83mm/3.26 inches apart) for clamping the base of the device into place, plus two 5mm/0.2 inch holes at each end of the bracket for fixing the bracket to the ceiling tile.

Two M4 x 35mm Phillips head screws are included per bracket.

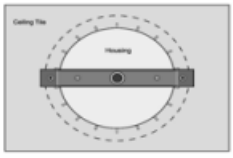
Mounting Information

1. Cut a 123mm (4.8 inch) diameter hole n the tile where the device is to be flush mounted.

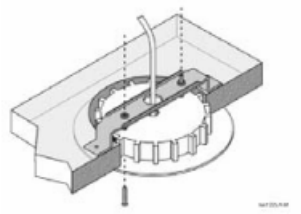


2. Pull the applicable cable(s) through the cable entry hole of the bracket and into the base of the reader or exciter.

3. Insert the bracket through the mounting hole placing it on top of the ceiling tile. Position it so that the bracket is firmly supported by the ceiling tile.



4. Insert the base of the reader/ exciter into the mounting hole. Next, screw the base to the mounting bracket place using the 2 supplied M4 x 35mm Philips head screws. Ensure that the screw heads are recessed inside the screw holes. If not the device will not close properly and damage may occur.



5. Connect the cable(s) to the reader/exciter; then insert the device back into its base.

Figure A1.10 Mounting bracket description and short mounting information

ANNEX 2. Separated study for the i-Walker case.

A2.1. Introduction

The FATE system will be able to detect falls both inside and outside the home. Moreover for elderly suffering the biggest gait difficulties that routinely use an assistive device for ambulation, such as a walker, the system will be complemented by the i-Walker, an intelligent walker designed to minimize the risk of falls of those elders.

To this end we will enrol elderly with high risk of fall living in nursing homes; from the literature this population fall more often than those who are living in community. Approximately half of nursing home residents fall annually, two to three times that of community residents.

Elderly subjects that will be enrolled in this branch of the study are not able to walk without a device and use a roller to move independently. They are affected by gait and balance difficulties often due to a neurological disorder, such as ictus, Parkinson disease, etc.

They will be provided with the fall detector and moreover traditional walker will be substituted by the i-Walker. I-Walker, besides detecting falls, will support the user reaching stand up position and relieving him from doing a determined percentage of the necessary forces. Moreover it can force the user to apply a forward pushing force in the handlers in a downhill situation.

A2.2. Study equipment

The i-Walker is a robotic rollator developed by UPC, it is based on a standard walker's frame enhanced with the following sensors and components:

- **6 force sensors:** To detect in both handlebars the 2 force components: Longitudinal (Forward/Pushing), Vertical (Leaning/Resting) and the normal forces of the floor.
- **Dual axis accelerometer:** The accelerometer sensor is attached to the Walker frame and measures continuously the (x,y) components of the acceleration appearing while using the walker.
- **Odometer:** It consists in encoder embedded on the wheel that reports the travelled distance for each rear wheel. The trajectory can be recovered from these data.
- **Processing unit:** Distributed microcontroller architecture samples periodically the forces, acceleration and the travelled distance. A software module running in the microcontroller logs these samples.
- **Communication unit:** It is composed by a Bluetooth and a serial communication link module used as the interface to periodically gather the logged information by an assistant.
- **Power unit:** The i-Walker use standards batteries as the only power supply.
- **Output interface:** The i-Walker is provided with some LEDs in the handlebars that permit the user to inspect the status of the battery at any time.

The i-Walker offers the following services:

- Maintain an almost constant pushing force of the i-Walker, independently of the path as prescribed by medical considerations.
- Record in real time (every 0.1s): forces exerted by the user while using it, the 2D trajectory and travelled distance, the acceleration suffered by the i-Walker while driving it.
- Moreover a database and software application will be tailored to analysis the information, (how the participant lays onto the walker and how much force exerts on the handlebars while following path, the experimented acceleration by the i-Walker during the walk).

As depicted in
Figure A2.1, in the normal operation of the walker, the user must apply pushing or pulling forces in the handlers to move around. The strategy of helping the user consists on relieving him from doing a determined percentage of the necessary forces. Moreover it can force the user to apply a forward pushing force in the handlers in a downhill situation instead of pulling force that can be *less* safe. The i-Walker operates passively; it never pulls the user with its motors and only provides support when the user is actively moving the i-Walker.

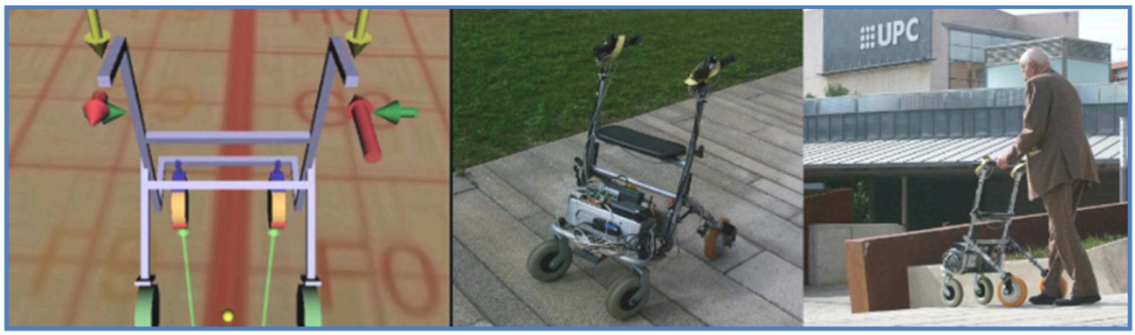


Figure A2.1. i-Walker operating mode.

A doctor can determine both the amount of helping percentage and braking force in each hand. Both strategies are not exclusive: we can have the user pushing the *i*-Walker going downhill and at the same time the walker relieving him from part of the necessary pulling/pushing force to move around.

The *i*-Walker will be essentially used as a good and advanced help to the personal mobility, because the characteristics of the element.

A2.3. Objectives

To observe in a population at high risk of fall if the use of an *i*-Walker, independently of the presence of the wearable fall detector, can reduce the frequency of falls, fear of falling, enhance independence and measure user satisfaction.

A2.4. Study population

A2.4.1. Number of participants

The study will be conducted on 24 elderly participants (12 users with *i*-Walker + 12 users with traditional walker) living in nursing homes in Spain.

A2.4.2. Eligibility criteria

Inclusion criteria:

- Older than 64 years.
- At least 1 falls in the previous 6 months.
- Ability to walk with walker without assistance.
- No changes in cohabitation status from the last fall, and no plans for changing it.
- 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:

- Unavailability of technical conditions.
- Unable to operate the FATE system after 2 training sessions.
- Carriers of implanted electronic devices: cardiac pacemaker, implantable automatic defibrillator, etc.
- Known mental disease, such as dementia, according to clinical criteria -DSM-IV-TR and MMSE score ≤24 or neuropsychiatric disorders.
- Acute medical conditions.
- Chronic condition leading to more than one hospital admission in the last year.
- Participating in another clinical trial.
- 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.

A2.4.3. Sampling procedure / recruitment

The sponsor in each area will be responsible of sampling recruitment. The sample will be selected by convenience sampling of people living in nursing homes. Once they have been selected, a family member, a relative or a neighbour will be contacted and offered to participate in the study.

A2.5. Study design

The study is an experimental clinical trial with a cross over design.

All the participants in the study will be followed during 12 months. All of them will use the i-walker (intervention period) for six months and will be under “standard care” (traditional walker) for another six months (control period). Thus each participant will be under research

(under the study measurements and observations), both when using the system and when not using the system, being each participant "control" of him for statistical analysis purposes. These two periods will be separated by 4 months when the participants will not be observed or contacted by the researchers at all.

The sample (24 participants) will be selected by convenience sampling of the population living in nursing home already using a device for ambulation, such as a walker.

Participants who satisfy the inclusion criteria previously defined will be randomly assigned to 2 groups:

- 12 participants will be provided with wearable fall detector and with i-walker.
- 12 participants will be provided with wearable fall detector and with traditional walker.

A2.5.1 Outcome measurements

The primary outcome measures are:

- Fall detection.
- Increasing activity and functional capacity.
- Improving gait and balance.
- Improving quality of live.
- Increasing the number of interventions for fall risk reduction.
- Increasing contacts and surveillance by primary care physicians.
- Evaluate usability of the system and user satisfaction.

Each variable had to be measured by the means of one or several instruments or indicators, which are the following:

- Falls reduction (number of falls).
- Fear of falling (Falls Efficacy Scale [1]).
- Balance and gait (Tinetti's scale [2]).
- Increasing activity (Stanford seven-day physical activity recall questionnaire [3]).
- Increasing functionality (Barthel index [4], Lawton index [5] AADL questionnaire, Up & Go [6]).
- Number of contacts with the caretaker.
- Contacts with emergency services.
- Contacts with GP.
- Number of preventive measures implemented.
- Number of rehab prescriptions.
- Quality of live (SF-36) [7].
- QUEST (Quebec User Evaluation of Satisfaction with Assistive Technologies) [8] – participant's and carers –
- Semi-structured diary on usability for participant's and teleoperators.

A2.5.2. Training of the researchers

A principal investigator (PI) is responsible of the study. This PI may delegate part of the work in as many co-investigators, as he considers necessary.

The PI and the co-investigators will receive a 1 day training session, comprising theoretical sessions including guidelines and instructions of all the instruments and questions of the Case Report From (CRF), and practical sessions with actors as participant's who behave according a number of pre-established situations which will serve an example of the most relevant cases.

A2.5.3. Screening visit

Participant candidates will be contacted by phone the PI or a co-investigator who will gather initial data in order to pre-check some inclusion/exclusion criteria: demographic data (age), social data (contact person), functional data (ability to walk) and health data (number of falls, chronic conditions, hospital admissions, implanted electronic devices).

If the participants fulfil the initial inclusion criteria they will be scheduled for the screening visit. This visit will take place at the participant's nursing home. This visit will consist of an interview that will last about 30 minutes, its main objective is to assess whether the potential participant fulfils the inclusion or exclusion criteria. In this visit the participants will be provided with the "participant information sheet" and the informed consent form. The researcher will explain the study purpose, procedures, possible risk, benefits and subject responsibilities to the potential participant. The subjects will be given the opportunity to evaluate these documents in detail and will be allowed to ask the investigator any question regarding the study.

Firstly identification data will be validated and the signed and dated informed consent forms will be collected and reviewed. During the interview, the required social and demographic data will be gathered according to the guidelines and forms included in the CRF (case report forms). The functional status will be assessed by using selected ADL scales included in the CRF (Barthel's index), fall risk will be evaluated by the self-reported number of falls in the previous six months. The cognitive status will be evaluated using the Mini-Mental State Examination. The past medical history will be recorded, including the list of chronic conditions and drugs. Present state of wellness (absence of acute disease) of the participant will be also recorded, as reported by the participants.

Finally the technical requirements for installation of the FATE system together with i-walker will be checked. This technical requirements check may be carried out in a separate visit, according to the scheduling and availability of the technical researchers.

A2.5.4. Intervention allocation

All the participants' in a given setting will be randomly assigned to receive or to not receive the intervention first. The recruitment coordinator for all the pilots' site will perform the randomization. Each pilot site will send to the coordinator the encoded names of the selected participants, and he will determine whether or not the participants in each pilot site participate in the intervention period first. As mentioned earlier fifty per cent of the participants in each pilot site will be assigned to receive intervention first.

Those participants assigned to receive the intervention will be scheduled for the "Pre-intervention visit, Implementation of the system user training" visit (see below). The participants assigned to start with the control period will be scheduled for the "Pre-control period basal" visit.

A2.5.5. Pre-control period basal visit

This visit can be performed the same day as the "screening visit", once the eligibility criteria have been confirmed. The purpose of this visit is to establish the participant's baseline regarding important variables that will be used to estimate the effectiveness of the FATE system.

The PI or a sub-investigator at the participant's nursing home will conduct this visit. The visit will comprise an interview and a physical exam that will last about 45 minutes. During the visit, the researchers will assess fear of falling (FES), balance and gait (Tinetti), functionality (Barthel's, Lawton's, AADL questionnaire, timed Get Up & Go test) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF.

The participant's designated contact person will be also contacted, and will be asked to complete a structured questionnaire involving aspects of the care and/or relationship with the participant, including time devoted to this care or relationship.

Carers and relevant personnel in the care service will be contacted to take part in a structured interview involving aspects of the care including time devoted to this care.

A2.5.6. Control period (unexposed to system)

All the participants will be followed during a period of 6 months while not using the system. During this period, they will be phoned weekly by a researcher, who will gather information about the number of falls and the time to rescue (Structured questionnaire on falls and long lie), the use of sanitary resources (Structured questionnaire on the use of health services), the Professional-participant interaction aspects (including number of interventions prescribed on fall's risk and rehab programs initiated) and the number and severity of possible adverse effects.

The participant's will also receive a monthly visit, in which a researcher will gather information about the changes in the medical treatment (the addition or discontinuation of drugs that could cause falls) and the level of physical activity (Stanford seven-day physical activity recall questionnaire). During this period the participant will keep a diary on fall events and other adverse effects, which will be checked by the investigators in the monthly visit. The monthly visit will last about 45 minutes.

A2.5.7. Post-control period visit (participant)

The last day of the control period, the researchers will visit the participant. The PI or a sub-investigator at the participant's nursing home will conduct this visit. The purpose of this visit is to track changes from baseline in the variables registered in the pre-control visit. The visit will comprise an interview and a physical exam that will last about 45 minutes. During the visit, the researchers will assess fear of falling (FES), balance and gait (Tinetti), functionality (Barthel, Lawton, AADL, timed Get Up & Go) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF. If it is convenient then, this visit can be coincident with the last monthly visit of the control period.

The contact person of the participant will be also contacted, and will be asked to complete a structured questionnaire inquiring about aspects of the care and/or relationship with the participant, including time devoted to this care or relationship.

Carers and relevant personnel in the care service will be contacted to take part in a structured interview involving aspects of the care including time devoted to this care.

A2.5.8. Wash-up period

Between the intervention and control periods, there will be a wash-up period, in which no follow up activities or contacts with the participant's will be done. This period will last for 4 months. The purpose of the wash-up period is to let the participants to return to their basal point, allowing the clearing of habits acquired by the intervention or the observation. This period is necessary before further observation of the participant; otherwise the second observation could be affected by carry-on effects of the first observation.

A2.5.9. Pre-intervention visit, implementation of the system user training

Before the intervention period starts, the system will be installed at the participants' nursing home. To do so, the required technical personnel will attend the nursing home. Once the system is properly deployed and tested, the participant will be trained in using the system. This visit can be performed the same day than screening visit in the case of the participant's that are randomized to receive the intervention first.

All the users of the system will receive clearly defined protocols and user manuals written in their own language.

After the training process, the QUEST questionnaire will be used to assess usability and satisfaction, and the structured interview on FATE's usability aspects will be performed.

A telephone number for any doubts and technical incidences will be given to the participant's, 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 FATE project will provide timely support when necessary at the local places of the pilots.

In the same visit, sanitary personnel specifically trained to do so, will collect information about fear of falling (FES), balance and gait (Tinetti), functionality (Barthel, Lawton, AADL questionnaire, Up & Go) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF. The purpose of these data collection is to establish the basal set point of these variables before the use of the FATE system.

If training is not successful in the first visit, 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 after two different training sessions will be excluded of the study.

The contact person of the participant will be also contacted, and will be asked to complete a structured questionnaire inquiring aspects of the care and/or relationship with the participant, including time devoted to this care or relationship.

Carers and relevant personnel in the care service will be contacted to take part in a structured interview involving aspects of the care including time devoted to this care.

A2.5.10. Intervention period (participant)

The participants will start using the system in their routine life for a period of six months while they are under the research observation.

All the technical incidences including lost data or erroneous data will be recorded by the research team, as well as their severity, the actions needed to solve them and the timing of these actions. Any possible events involving loss of confidentiality will be also registered. All the data sent by the system will be recorded in a database for later analysis. One day every week the participants will also record in the "technical section" of their "study-diary", every time they switch on or off the system or any of its components, and every time they lie or get up from bed. This recording will help the researchers to estimate the amount of data that is really being transmitted. Additionally, participants will record in the corresponding section of their study-diary all the usability problems they may found at any time.

Similarly during control period a researcher will phone the participant weekly.

During this period the participants will record all fall events and any adverse effects in their "study-diary". The participants will also receive a monthly visit, in which a researcher will gather information about the changes in the medical treatment (the addition or discontinuation of drugs that could cause falls) and the level of physical activity (Stanford seven-day physical activity recall questionnaire). In this monthly visit the researchers will check and record all the sections of the participant's study diary, and will download the data of the activity monitor. The monthly visit will last about 1 hour.

A2.5.11. Intervention period (carers at nursing homes)

During the intervention period the carers at nursing homes monitoring the participant will act according the action protocols specifically defined for each pilot site. Each alarm received and each action taken will be stored in a database for later analysis.

On weekly basis, the carers at nursing homes will fill the usability section of their study diary to register all usability problems detected.

On daily basis, the carers at nursing homes will fill the technical incidence section of their study diary, in order to report any technical incidence that may occur.

A2.5.12. Post-intervention period visit (participant)

The last day of the intervention period, the researchers will visit the participant's. The PI or a sub-investigator at the participant's nursing home will conduct this visit. The visit will comprise an interview and a physical performance exam and overall will last about 45 minutes. During the visit, the researchers will assess fear of falling (FES), balance and gait (Tinetti), functionality (Barthel, Lawton, AADL questionnaires, Up & Go) and quality of live (SF-36) by using the appropriate battery of tools included in the CRF. During this visit all of the technical equipment deployed in the house will also be collected, and the QUEST questionnaire and the structured interview on FATE's usability aspects will also be performed.

The designated contact person of the participant will be also contacted, and will be asked to complete a structured questionnaire inquiring aspects of the care and/or relationship with the participant, including time devoted to this care or relationship.

Carers and relevant personnel in the care service will be contacted to take part in a structured interview involving aspects of the care including time devoted to this care.

A2.5.13. Post-intervention period visit (carers and stake holders)

All carers participating in the intervention period will answer the Quebec User Evaluation of Satisfaction with Assistive Technologies (QUEST) [8]. The usability and technical incidences section of their study diary will also be reviewed, and the study diary collected.

After the intervention period, the carers and the relevant personnel in the different care services will be contacted to take part in a structured interview, in order to gather their impressions and degree of satisfaction with the FATE system.

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