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[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

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Glossary

CRF: Case Report Form
IPR: Intellectual property rights
MDD: Medical devices directive

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1. Introduction

The goal of this document is to summarise the major conclusions and results obtained within the framework of the FATE project. Even if the conclusions corresponding to specific parts of the project have been included in previous Deliverables, this document will encapsulate them in order to provide a global view of the achievements and lessons learned. References to the documents where all the details are included will be provided, but the document will be kept as self-contained as possible.

2. Pilot design

The principal goal of the FATE project is to validate an ICT solution for the efficient detection of falls in elderly people. Therefore, when designing the pilots special attention was paid to establish a scientific methodology that should permit the strict assessment of the FATE system.

The FATE system was tested in three countries, Spain, Italy and Ireland, and involved more than 265 users. The trial was organised around five different pilots, where not only the validity of the FATE system was assessed, but also its integration with different care services. The pilot organisation was the following:

- **Italy:**
  - One pilot, encompassing 90 users, in a rehabilitation hospital (Fondazione Santa Lucia in Rome). In this pilot the users were experiencing the fall detector and the *i*-Walker rollator.
  - One pilot, encompassing 50 users, managed by COOSS Marche. This pilot was carried out in rural areas, and the telecare service provided was based on local proximity.
- **Ireland:**
  - One pilot, encompassing 50 users, managed by Tunstall Emergency Response. In this case the service model tested corresponded to a nation-wide telecare system.
- **Spain:**
  - One pilot, encompassing 25 users, in the area of Barcelona city.
  - One pilot, encompassing 50 users, managed by Hospital Clínic Provincial de Barcelona (HCPB), a tertiary hospital providing service to more than 300000 people in the area around Barcelona. For this pilot, specific instruments and goals were defined apart from the common ones established for the rest of the pilots.
  - Both pilots were managed by Sistema d'Emergències Mèdiques (SEM), a large-scale medical emergency system providing service to more than 7 million people and attending more than one million emergencies a year.

The inclusion criteria established for the people participating in the pilots were the following:

- 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.

Additionally, the following exclusion criteria were set:

- Lack of any of the following technical conditions: o 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.

All the pilots except those carried out at Fondazione Santa Lucia were organised as a crossover design, meaning that each participant is its own control. The users were undergoing a 6-month intervention phase and a 6-month control phase, both separated by a 3-month washout period. The pilot carried out at Fondazione Santa Lucia was constituted by 30 users who underwent a 3-month intervention period and 60 additional users who were assigned to a 3-month control period.

The first important aspect to highlight from the FATE pilots is that it is rather difficult to perform a recruitment process for people who should meet the inclusion criteria for a fall detection and prevention pilot. The ratio between screened participants and the recruited ones was approximately 20:1. This caused some delays for the start of the pilots.

Another important aspect to consider in an experimental setup involving a significant amount of users in three different countries is the coordination and follow-up of the pilot activities. To facilitate the coordination tasks three measures were setup:

- A weekly Skype call was organised between all the partners involved in the pilots while the piloting activity was running. This permitted the early detection of issues or deviations and plan appropriate contingency measures.
- A pilot periodic report was designed in order to account for the major incidences occurring in a pilot (number of users, dropouts and technical issues). Annex I includes the pilot periodic report model that was used in the FATE pilots. This report was filled and issued to the project coordinator by each pilot site every month.

- An issue register was designed in order to account for the major issues arising during the pilot activity, so as to permit the early detection of important aspects that need a contingency measure. Every pilot site filled and sent to the coordinator this issue register every month. Annex II includes the issue register model that was used in the FATE pilots.

In addition to the previous measures, a risk register was defined for the pilots. Annex III presents the last version of the FATE risk register.

In order to facilitate the compilation of the user data and the consequent analysis, a web-based application was developed in order to permit the researchers participating in the pilots to enter the Case Report Forms (CRFs) in electronic format.

Figure 1 shows the user interface of this application. The web application was developed under HTML5 and CRF data was saved into a MySQL server.

Figure 1. Web-based application to enter the CRFs.

Regarding the definition of the experimental protocol, an important issue has been observed in the FATE project. Since the study was a crossover one, a participant who is assigned to the control group in the first round of the pilots has to wait during 9 months (6 as control + 3 for the wash-out) until entering in the intervention group. This has produced several dropouts, that are understandable since the participants in the FATE pilot are typically frail people, and they don’t feel very comfortable following a protocol during 9 months without experiencing the actual system.

Since the FATE system is rather complex for people not used to manage technical setups, user training is an important aspect both for avoiding early dropouts and for improving the validation of the system. Special emphasis has been put in the FATE project to this aspect, as it is demonstrated by the reduction in the dropout rate in the second round of the pilots with respect to that observed in the first round.

The careful design of the experimental protocol used in the FATE pilots has permitted not only to validate the system, but also to construct a rich database from which scientific evidences about aspects related with ageing will be extracted. This will produce several high-quality scientific publications that will be written and submitted after the end of the project.

The details of the pilot definition and the corresponding experimental protocol can be found in Deliverable *D1.3 – Complete pilot definition*.

3. Technical conclusions

Figure 2 shows the overall organisation of the complete FATE system that was used in the pilots. The *i*-Walker rollator is not included in the figure, since it is an independent component that was used only in the pilot carried out at Fondazione Santa Lucia.

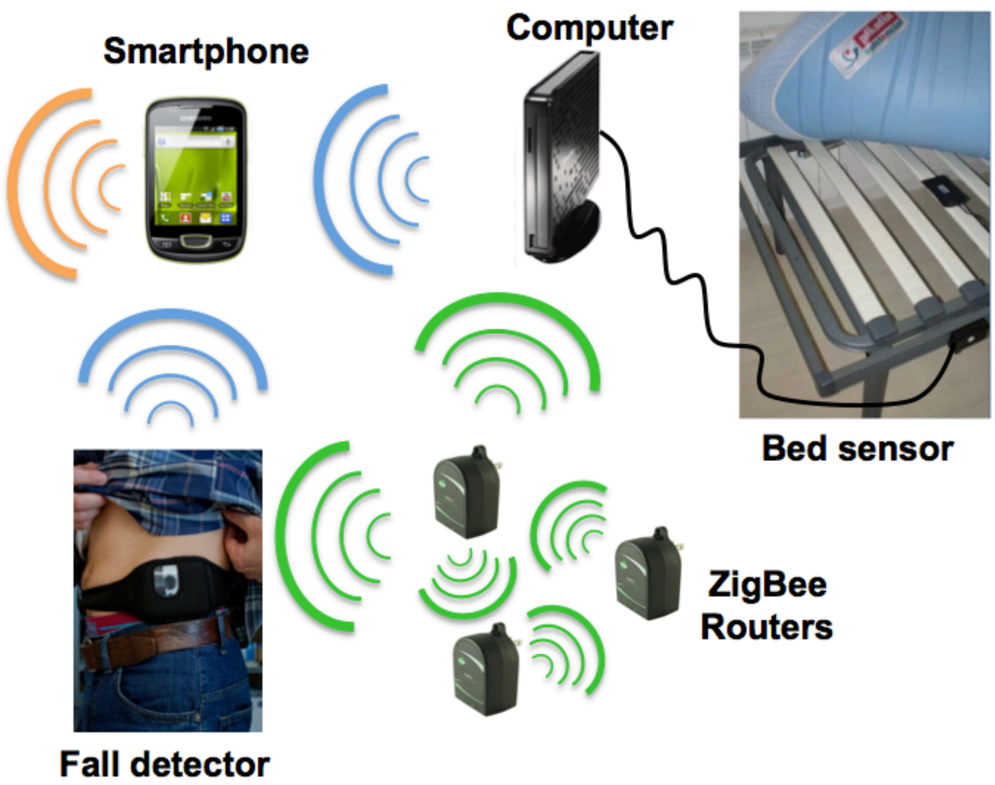

Figure 2. Overall organisation of the FATE system.

The first important aspect worth mentioning about the FATE system is the complexity associated with its installation at user's home. This implies that a typical FATE installation takes between two and three hours. The complexity is due to the fact that it is necessary to guarantee a correct ZigBee network coverage at user's home. This implies that a coverage map has to be constructed for each installation and, depending on the specific structure of the home, this process may take more or less time. Additionally, if this coverage is not guaranteed for every zone in user's home, some alarms may be generated if the user is not carrying on the smartphone.

Another issue that was detected in some cases during the pilot deployment was the "*technical invasion*" feeling current elderly people have when the system is installed. Since they are not able to fully understand the purpose of all the components, in some cases they feel overwhelmed by the FATE setup. Furthermore, since some components are installed in user's bedroom, in some cases the participants also fear that they may have a negative impact on their health (typically, because of radiation side effects). These aspects caused several dropouts during the pilots.

The inherent complexity of the FATE system also provoked several unintentional system turn-offs. These were rising when somebody (typically, the user or the cleaning servant) unplugged the computer or some of the ZigBee routers during routine cleaning activities and forgot to plug them afterwards. This forced several visits to restart the system.

As it has been pointed out in the previous section, the system's complexity had also a negative impact on user training, being an incorrect use of the FATE system the most typical source for the alarms arriving to the call centres.

Since the FATE system relies on several components that cannot be totally controlled (i.e., the operating system of the smartphone and the computer) the inherent instabilities of those components caused some system turn-offs that forced additional visits to restart the system.

These last two aspects have to be taken into account when calculating the maintenance overhead in a system such as FATE, since they imply that technical staff should perform regular supervision tasks in order to guarantee the correct operation of the system.

There is also an important technical aspect that not only applies to the FATE system, but to any health service that relies on ICT. Since the alarms are transmitted using commercial cellular networks, the correct delivery of these alarms depends on the coverage provided by the telecomm providers. Even if this coverage can be verified at user's home, it is typically fluctuating outdoors, and in specific cases, especially in rural areas, can be very low. This may impact the overall service provided to the user, and therefore it is of utmost importance that the service is associated with a reliable telecomm provider.

Some of the components of the FATE system also pose usability concerns. Among them it is worth mentioning the panic button of the fall detector. In order to avoid false positives the membrane covering the physical switch was designed with a hard touch. This prevented the user from feeling when a correct press was issued, and as a consequence several false alarms were generated when the user tried to cancel false positives.

Some other usability concerns are related with the user interface of the FATE system. For instance, some users didn't like the light indicators included in the fall detector, since they are visible when the user is outdoors and other people may realise that the user is wearing a *strange* device (even if the fall detector is worn beneath clothes). The sound emitted by the fall detector in the case of an emergency also raised some usability issues. It was difficult for some users to hear this alarm sound, and even if the frequency of this sound was fine tuned during the second round of the pilots, it was difficult to find a satisfactory solution for users who typically have some kind of hearing impairment. It is worth noting that, in order to fit the dimensions of the fall detector, the speaker producing this sound alarm has to be small, and this prevent it from covering a wide range of acoustic frequencies.

Another aspect that generated concerns among the users was the charging process. Since the fall detector contains a rechargeable battery as a power supply, a charging process has to take place every day. Even though the charger contacts were designed to facilitate this process, for some users it was difficult to be sure when the charging process was in place. This caused the discharge of the device and a consequent alarm indicating that the sensor is no more present in the system.

Regarding the bed sensor included in the FATE system, even if it was found to be very sensitive, the overall usefulness of this component for detecting falls was found to be marginal. This component was the second cause of fall alarms, generated by users who did not comply with the sleeping habits they specified during the recruitment. However, it is also worth mentioning that some users (and especially their relatives) feel much safer if this component is integrated in a fall detection system.

Bearing in mind the technical issues detected during the pilots, it was decided that a technically viable and user friendly fall detection system should have the following features:

- Simple and unobtrusive sensor. This implies that it should be light and small enough in order to not be detected by external observers.
- Extremely simple user interface and maintenance. No buttons or switches and powered by replaceable standard batteries, so that there is no need for a dedicated charger.
- The sensor should be managed by the user's smartphone by means of a specific application, so that there is no need for a dedicated one. The sensor communicates with the smartphone by means of a Bluetooth wireless link.

These features have been included in the commercial version of the fall detector derived from the FATE project, which is depicted in Figure 3.

Figure 3. Commercial version of the fall detector.

Finally, there is a very important finding resulting from the project. The FATE system has been seamlessly integrated in a wide range of care services, from local support services to large-scale emergency services. Therefore, its scalability has been demonstrated, and this will facilitate its eventual integration in any kind of care services/units.

4. Performance results

The major goal of the FATE project was to develop a reliable fall detector for elderly people. Regarding the robustness of the FATE system, the previous section has highlighted some technical issues that may impact negatively on its reliability. However, apart from the lack of cellular network coverage, the FATE system was found to be very robust, since only 45 interventions were needed to fix a specific system component. If we compare this number with the number of days the system was operative in the five pilot sites, more than 30000, we can observe that the average incidence rate is one every 683 days, *i.e.*, almost one every two years. Even if the maintenance costs associated with these issues have to be taken into account when planning its commercial introduction, they have been found to be acceptable.

From a validity point of view, the **FATE pilots have demonstrated that the fall detector has sensitivity higher than 95%, and specificity higher than 99%.** There was only a false negative found in the pilots, corresponding to a person experiencing a fall inside a lift. These numbers make the fall detector used in the FATE system comparable, and in most cases superior to the commercial solutions available in the market.

5. Medical and public health results

Even if the primary goal of the FATE project was the development of a reliable fall detector for the elderly, it has also secondary objectives related to the health condition of the users. Among them, it is worth highlighting the following major outcomes found after analysing the data produced by the FATE pilots (the complete analysis can be found in Deliverable *D3.3 – Pilot report for the second round of tests*):

- A statistically significant reduction in the fear of falling indicator (FES scale) is found on the participants using the FATE system (intervention group).
- A statistically significant improvement in the Barthel's index, which measures the independence for basic activities of daily living, is found on the participants using the FATE system (intervention group).
- A statistically significant improvement in the balance and gait (Tinetti's scale) is found on the participants using the FATE system (intervention group).

These results demonstrate that a fall detection system like that developed in the FATE project may have a direct positive impact on the health of elderly people. Just as an example, one of the users of the pilot at Hospital Clinic decided to abandon the study because his physical condition improved so much that the continuation in the study was not considered necessary for the user.

As a consequence, the FATE project has demonstrated that the FATE system is not only an efficient tool for fall detection, but also for fall prevention.

6. Dissemination results

As it is covered in detail in Deliverable *D6.5 – Final report on dissemination activities*, the FATE project has produced a large amount of dissemination activities. Among them, it is worth highlighting the following ones:

- A video was created by the Reuters agency and distributed to a worldwide audience about the major features of the FATE project. The reference to this video can be found at: https://ec.europa.eu/digital-agenda/en/news/reuters-video-report-eu-funded-research-project-fate-fall-detector-elderly-speeds-emergency
- The company that will bring to the market the fall detector derived from that used in the FATE project was present with a dedicated booth at the European Summit on

Innovation for Active & Healthy Ageing that was held in Brussels on March 9-10, 2015.

- News related to the FATE project has appeared in the major TV, journal and radio channels in Spain.
- The FATE project has been present in major events related to eHealth and ageing.
- A specific FATE workshop was organised in Barcelona on May 2015.

Apart from the typical dissemination carried out through the project's web page, the FATE project has devoted an important effort to its presence on the major social networks (Facebook and Twitter). The activity of the project in these networks has been especially important during the last period of the project, when the project results were compiled.

During the framework of the project two scientific publications were produced. These publications addressed basically the goals of the project and the experimental design of the pilots. After the analysis of the data produced by the pilots has completed the consortium plans to write and submit high-quality scientific papers to medical journals. Additionally, the careful design of the experiments carried out in the FATE project and the quality control measures adopted during data collection has permitted the FATE project to compile a high-quality database that will be exploited for further falls-related analyses.

7. Innovation and market approach results

The spirit of the CIP framework is not only to validate a viable technology or solution, but also to encourage a consortium to take the steps to bring it as soon as possible to the market.

The first step towards defining a commercial solution consists in establishing the corresponding IPR and exploitation rights. The agreements reached within the consortium about these aspects are specified in Deliverable *D5.4 – Analysis of IPR-related issues within the FATE consortium*.

The second most important step towards a market approach consists in defining the path towards the achievement of CE-marking. In this respect, and considering the fall detector device, two alternatives have been considered:

- A consumer product version of the device.
- A medical device certification.

The consumer product version of the device implies compliance with the following directives:

- Electromagnetic compatibility directive (2004/108/EC).
- Radio equipment and telecommunications terminal equipment directive (1995/5/EC).
- Restriction of the use of certain hazardous substances in electrical and electronic equipment directive (2011/65/EU).

The medical device version of the device implies compliance with the following directives:

- Medical devices directive (93/42/EEC).
- Electromagnetic compatibility directive (2004/108/EC).
- Radio equipment and telecommunications terminal equipment directive (1995/5/EC).

- Restriction of the use of certain hazardous substances in electrical and electronic equipment directive (2011/65/EU).

Within the framework of the FATE project, a start-up company has been created, Sense4Care S.L., to which UPC has transferred the exploitation rights corresponding to the fall detector algorithm used in the FATE system. People belonging to the UPC team working in the FATE project own this company, among others. From the experience gained in the FATE project, Sense4Care has been able, using its own resources, to:

- Define an appropriate market segment where a fall detector device may be disruptive.
- Define the specifications needed for such a fall detector device.
- Design a commercial version of a fall detector device.
- Produce a pre-production series of the device.
- Develop a business model based on this device.
- Establish initial commercial contacts with potential distributors of the device.
- Obtain all the certifications needed for the CE-marking of the consumer product version of the device. Appendix IV contains the CE-marking conformity declaration of Sense4Care about this product.
- Specify and purchase an Android application able to manage the fall detector device.

Additionally, the FATE project has analysed the steps required for an eventual medical device CE-marking of the fall detector resulting from the FATE project. The corresponding regulatory compliance report is included in Deliverable *D5.7 – Action plan for CE-marking*. The remaining activities to be fulfilled in order to achieve a medical device certification of the fall detector are those summarised in Table 1.

Table 1. Remaining activities for the CE-marking of the fall detector as a medical device.

Item	Activity
1	MDD approved quality management system
2	Continuous update of table-of-content technical file
3	Update of requirements specifications
4	Update of the intended purpose
5	Assess validity of MDD classification
6	Update of MDD Product Description including biocompatibility analysis
7	Update of Checklist Essential Requirements
8	Re-assessment of applicable standards
9	Update of risk assessment
10	Re-perform verification and validation
11	Draw up a Declaration of conformity

In summary, at the end of the FATE project there will be a commercial CE-marked product that will be sold through a company that has been constituted within the framework of the project. Potential distributors are already testing pre-production units of this product in two countries, UK and Israel. Direct sales through the web page of Sense4Care will be possible from July 2015.

Even if the first entry to the market will be similar to that defined in the FATE project, the roadmap for the product includes alternatives that do not require a user's smartphone to communicate the alarms, thus making the final product more transparent from the user side.

Another possibility for bringing the fall detector to the market is the integration of the fall detection algorithm into third-party products under a licensing agreement. MLGtech in Israel is currently exploring this possibility after the first pre-production unit evaluation.

Regarding the *i*-Walker device, two possibilities are currently under evaluation:

- B2B exploitation revenues from:
    - Service usage transferred/sold to care service provisioning organizations, based on a pay-per-use (*i.e.* rehabilitation session) cost model
    - Partly from governments that will subsidize the use of the service (by public organizations) and partly from other streams and organizations (*e.g.* private health organizations and care services providers). In such a case the *i*-Walker services will be provided as a service and UPC act as an Application Service Provider.
    - Cost sharing among public/private social and health care service provisioning and end users
    - The device and the software are provided under a cession agreement free of charge. Approximately each user training session would be charged 2€ (including *i*-Walker use and configuration, data recording, transfer, post-processing and displaying).

- Indirect exploitation: The *i*-Walker as a robotics device has the confluence of various technologies that can be separately sold as components to be integrated in any rollator frame with minimum mechanical modifications. These components susceptible to be sold are:
    - Motor, electronics and control.
    - Handlerbars and electronics.

8. Conclusions

This document has summarised the major achievements of the FATE project. After analysing the pilots' results, we have demonstrated that the FATE system is not only a reliable solution, in most cases improving already available commercial services, for detecting falls in elderly people, but that it is also a useful instrument for fall prevention.

The lessons learned from the FATE pilots have permitted to define a proper commercial solution for fall detection that will be available as a consumer product in July 2015. Potential distributors are currently evaluating this solution.

The CE-marking procedures for the consumer version of the fall detector have been completed, and only a few steps are required in order to complete the CE-marking under the MDD directive.

Additionally, the careful design of the experimental protocol and the strict follow-up done along the pilot deployment has permitted the FATE project to compile a high-quality database from which significant results related to falls in elderly people will be extracted in the near future.

Therefore, it is our feeling that most of the ambitious goals that were set at the beginning of the project have been met.

Annex I. FATE Pilot periodic report model

Pilot Periodic Report

	Spain (SEM)	Spain (HCPB)	Ireland (NUIG)	Italy (COOSS)	Italy (FSL)
Pilot					

Period reported (Month/Year):

Date:

Responsible person:

1. User enrolment

- **Number of users in intervention:**
- **Number of users in control:**

2. User exit report for the period

User ID	Date	Reason	Replaced (Y/N)?

3. Technical issues for the period

User ID	Date	Description	Reported to support team (Y/N)?	Fixed (Y/N)?

Annex II. FATE issue register model

Issue register related to the risks

Reporting period:

Date:

Responsible person:

Description of issue	Number in current period (one month)	Total accumulated since pilot start	Comments
Dropouts in the control group			
Dropouts in the intervention group			
Falls detected by the sensor			
Falls detected by the sensor and reported to the call centre			
Falls registered by the users			
Sensors replaced due to impaired sensitivity			
Sensors replaced due to problems with the charger contacts			
Restart of the PC installed at user's home			
Intervention needed to plug a PC that was unplugged unintentionally			
Intervention needed to turn on the smartphone			
Intervention needed to unistall the bed sensor			
False alarms generated by a user not wearing the sensor correctly			
False alarms generated by a user pressing the panic button when not required			
False alarms generated by the user forgetting the night period (waking-up before the scheduled time) and forgetting the sensor and smartphone at home			
False alarms due to problems with the wireless network at home			
Falls reported by the users and not detected by the sensor			
Interventions to hide the lights of the devices			
Specific retraining sessions for the users			
Usability concerns with the smartphone			
Usability concerns with the sensor			
Usability concerns with the system			

Annex III. FATE risk register

Definitions

Impact (I)		Likelihood (L)		Risk Rating	
Extreme	5	Certain	5	Acceptable	0-4
Very High	4	Likely	4	Manageable	5-8
Medium	3	Possible	3	Serious	9-25
Low	2	Unlikely	2		
Negligible	1	Rare	1		
		Impossible	0		

Action required
No risk. No action (re-assess if any changes) 0
Low risk. Action only if inexpensive/easy to implement 0-4
Moderate risk. Action that is cost effective in reducing the risk & planned within a reasonable timescale 5-8
Significant risk. Urgent action to remove/reduce 9-15
High risk. Immediate action to remove/reduce risk 16-25

Register of key risks

Risk Ref	Description of risk	Date of assessment	Lead responsible	Risk assessment		Risk Rating (IxL)	Action required
				Impact (I)	Likelihood (L)		
TI	**Technical issues**						
TI 1	User technical training not completed satisfactorily in the pre-pilot phase	19/2/2013	SEM, COOSS, FSL, HCPB, NUIG	4	3	12	User should be discarded for the pilot and a new user from the eligible list should be enrolled
TI 2	User's home does not meet the technical requirements specified in the inclusion criteria	19/2/2013	SEM, COOSS, FSL, HCPB NUIG	4	3	12	User should be discarded for the pilot and a new user from the eligible list should be enrolled
TI 3	Poor cell phone coverage in the area where a user is living	19/2/2013	SEM, COOSS, FSL, HCPB, NUIG	4	3	12	User should be discarded for the pilot and a new user from the eligible list should be enrolled
TI 4	The fall detector generates too many false alarms	19/2/2013	SEM, COOSS, FSL, HCPB, NUIG	3	2	6	Contact the user and verify that the sensor is correctly worn. If this is the case, the fall sensor assigned to the user has to be replaced. The faulty fall sensor has to be sent to UPC for inspection. If the user is not wearing the sensor correctly, precise instructions must be provided in order to fix this issue
TI 5	The fall detector works properly but the fall sensor generates too many false alarms	19/2/2013	SEM, COOSS, FSL, HCPB, NUIG	4	2	8	A detailed report explaining the situation provoking the false alarm has to be generated. This report, together with the log files produced by the sensor and the PC has to be sent to FLOWLAB for inspection
TI 6	The smartphone generates an	9/7/2014	COOSS, TER,	4	3	12	COOSS, TER or FLOWLAB should visit user's home and

	alarm NO SENSOR, HIGH BATTERY exactly 30 minutes after the smartphone and sensor are connected to their chargers		FLOW LAB, FSL				verify that the PC is plugged and running and that the ZigBee wall routers are plugged
TI 7	After a complete charge during the night, the sensor stops working after a few hours	19/2/2013	COOS S, TER, FLOW LAB, FSL	4	2	8	The battery of the sensor is faulty and has to be replaced as soon as possible
TI 8	The sensor warms considerably during charging or the casing becomes brown	9/7/2014	COOS S, TER, FLOW LAB, FSL	4	2	8	The sensor has to be replaced as soon as possible and sent back to UPC in order to fix the charging contacts
TI 9	The panic button of the sensor is too hard to press	9/7/2014	COOS S, TER, FLOW LAB, FSL	4	2	8	The sensor has to be replaced by another with a softer panic button and has to be sent to UPC to fix the issue
TI 10	Secure repository exhibits access problems	19/2/2013	UPC	3	2	6	Any access problems have to be reported to UPC immediately in order to fix them
TI 11	CRF application server exhibits access problems	19/2/2013	UPC	3	2	6	Any access problems have to be reported to UPC immediately in order to fix them
TI 12	Unauthorised access to the server hosting the FATE database	19/2/2013	UPC	4	1	4	UPC will restore the access credentials to the server, and thereafter the last weekly backup will be stored
EI	**Pilot execution issues**						
EI 1	Pilot periodic reports are not issued on time	9/7/2014	UPC	4	1	4	UPC will remind the partners responsible for the pilots to fill and submit the monthly reports
EI 2	Electronic	9/7/2014	UPC	4	1	4	UPC will remind the

	CRFs are not filled on time						partners responsible for the pilots to fill and submit the monthly reports
EI 3	A user states intention to abandon the pilot	9/7/2014	SEM, COOS S, FSL, HCPB, NUIG	5	3	15	The user has to be approached as asked about the reason to abandon the pilot. If possible, the issue(s) provoking this situation have to be fixed immediately
EI 4	The defined communicatio n protocol with the call centre presents practical problems	19/2/2013	SEM, COOS S, FSL, TER	4	1	4	Analyse the problems raised and propose a modification in the communication protocol
EI 5	Incidences registered at the call centres are not reported on a weekly basis	9/7/2014	UPC	4	2	8	UPC will remind the call centres to provide the incidence reports with the planned periodicity
EI 6	A pilot site has no spare materials for the pilot	9/7/2014	COOS S, TER, FLOW LAB, FSL	4	1	4	Any faulty unit has to be sent to UPC, FLOWLAB, NUIG or ATEKNEA for immediate fixing and replacement
EI 7	A user in the control group express impatience about starting the intervention period (feels	9/7/2014	SEM, COOS S, FSL, HCPB, NUIG	4	3	12	The user has to be approached and the importance of the control period for the study has to be clearly explained
UI	User issues						
UI 1	The user does not wear the fall sensor correctly	9/7/2014	SEM, COOS S, FSL, HCPB, NUIG	4	4	16	The user has to be asked regularly about the ways the sensor is worn
UI 2	The user does not wear the fall sensor	9/7/2014	SEM, COOS S, FSL, HCPB, NUIG	4	4	16	The user has to be reminded at least once a month about the importance to wear the sensor during daytime and every day during the intervention period
UI 3	The user forgets the system	9/7/2014	SEM, COOS S, FSL,	4	4	16	The user has to be retrained. A basic reminder on

	operating instructions		HCPB, NUIG				emergency operation has to be issued at least once a month during one of the weekly calls
UI 4	The lights of the devices installed at home disturb the user	9/7/2014	COOS S, TER, FLOW LAB	4	4	16	The lights disturbing the user have to be hidden immediately
UI 5	The user is afraid about the electrical safety associated with the devices constituting the FATE system	9/7/2014	SEM, COOS S, FSL, HCPB, NUIG	4	3	12	A clear explanation has to be provided about the electrical safety certification passed by the FATE system
UI 6	The user is sensible to the radiations produced by the wireless components of the FATE system	9/7/2014	SEM, COOS S, FSL, HCPB, NUIG	4	3	12	A clear explanation has to be provided to the user indicating that, according to the current regulations and knowledge, the radiations produced by the FATE system are harmless. If the complaint persists the user should abandon the study
UI 7	The system operation is complex in an emergency situation	9/7/2014	UPC, FLOW LAB	4	3	12	The user interface has to be simplified
UI 8	The user reports that parts of the devices are lost	9/7/2014	COOS S, TER, FLOW LAB	4	2	8	The parts lost have to be replaced as soon as possible

Appendix IV. CE-marking conformity declaration

We

Sense4Care, S.L.,
Manuel Tomàs 26,
08800 - Vilanova i la Geltrú - Spain

declare under our sole responsibility that the following product

Equipment: Fall detector
Brand name: Angel4 Fall detection

is in conformity with the

Electromagnetic compatibility directive (2004/108/EC).
Radio equipment and telecommunications terminal equipment directive (1995/5/EC).
Restriction of the use of certain hazardous substances in electrical and electronic equipment directive (2011/65/EU).

and the following harmonised standards and technical specifications have been applied:

EMC: EN 61000-6-1:2007
EN 61000-6-3:2007 + A1:2012
EN 55016-2-3:2011 + A1:2011
EN 61000-4-2:2010
EN 6100-4-3:2007 + A1:2008 + A2:2011
RoHS: EN 50581:2012

Signed for and on behalf of Sense4Care, S.L.
Barcelona, 12th of June, 2015

Joan Cabestany, Member of the Board