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Lead Author:	Elias Kalamaras (CERTH)
Lead partners:	Elias Kalamaras, Andreas Vasilakis, Thomas Tegou, Eftychia Lakka, Konstantinos Votis, Konstantinos Moustakas (CERTH), Ioanna Petridou, Marina Polycarpou, Kimon Volikas (MATERIA), Vasilis Megalooikonomou, Ioannis Ellul, Dimitrios Vlachakis (UoP), Marina Kotsani, Athanasios Benetos (INSERM), Roberto Orselli (SMARTEX), Nhu Tram (AGE), Kosmas Petridis, Panagiotis Sabatakos (HYPERTECH)

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EXECUTIVE SUMMARY

This deliverable is a report of the work and outcomes of the FrailSafe tasks T1.2 “User requirements, clinical procedures and FrailSafe use cases” and T1.3 “FrailSafe UCD methodology”. It describes the requirements and the user needs that the FrailSafe system should fulfill. The requirements are considered from an end-user perspective, and are based on surveys conducted with representative end users. The outcomes of these surveys were used in order to define the specific use cases and scenarios of the system, which constitute a description of the system functionality. The deliverable also describes the User Centered Design (UCD) methodology that will be followed throughout the project, in order to ensure that the design and implementation conforms to the user needs.

The elicitation of the user needs and requirements was based on feedback from multiple sources, including the FrailSafe description of work document, the state-of-the-art works in the research fields related to FrailSafe, as described in deliverable D1.1, feedback from all partners in the plenary meetings and teleconferences, and finally the representative end users, through the conduction of surveys and focus groups.

The main goals of this deliverable are the following:

- The specification of the outcomes expected by the whole project;
- The identification of the end-user groups;
- The presentation of the user needs elicitation procedures that were followed;
- The analysis of the results of the user need elicitation procedures;
- The definition of the FrailSafe use cases and scenarios;
- The definition of the protocols for the evaluation studies;
- The definition of the User Centered Methodology that will be followed throughout the project.

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Date of delivery	**Contractual**	01/01/2017 (M12)	**Actual**	31/12/2016
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Nature	Report ☒	Demonstrator ☐	Other ☐	
Dissemination Level	Public ☒	Consortium ☐		
Abstract (for dissemination)	This deliverable reports the outcomes of tasks T1.2 and T1.3, regarding the collection of user requirements, the definition of the FrailSafe use cases and the User Centered Design (UCD) methodologies that will be followed. The user requirements were investigated through the analysis of feedback from end-users, via focus groups, interviews and surveys. The use cases are representative usage scenarios of the various system components, from the perspective of the identified end-user types. The use cases will be used for the design of the pilot evaluation scenarios, for which specific protocols will be followed, in order to ensure safety and ethics requirements. Finally, the UCD plan to be followed in FrailSafe is defined, which aims to ensure the end-user involvement throughout the development of the whole system and its components.			
Keywords	User requirements, use cases, evaluation protocols, UCD methodology			

Contributing authors (beneficiaries)	Elias Kalamaras, Andreas Vasilakis, Thomas Tegou, Eftychia Lakka, Konstantinos Votis, Konstantinos Moustakas (CERTH), Ioanna Petridou, Marina Polycarpou, Kimon Volikas (MATERIA), Vasilis Megalooikonomou, Ioannis Ellul, Dimitrios Vlachakis (UoP), Marina Kotsani, Athanasios Benetos (INSERM), Roberto Orselli (SMARTEX), Nhu Tram (AGE), Kosmas Petridis, Panagiotis Sabatakos (HYPERTECH)			
Responsible author(s)	Elias Kalamaras		**Email**	kalamar@iti.gr
	Beneficiary	CERTH	**Phone**	+30 2311 257715

TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND ACRONYMS 9

1 INTRODUCTION 1

2 POSITIONING OF THE DELIVERABLE IN FRAILSAFE OBJECTIVES 3

2.1 Frailty 3

2.2 Importance of user involvement for the fulfilment of the FrailSafe objectives 3

2.2.1 Medical objectives 4

2.2.2 Technological objectives 4

3 FRAILSAFE USER REQUIREMENTS 7

3.1 FrailSafe target user groups 7

3.2 Design of the requirements assessment campaigns 8

3.2.1 Initiation 8

3.2.2 Construction of questionnaires 8

3.2.3 Development of focus groups 8

3.3 Feedback collection and analysis 8

3.3.1 Project as a whole 11

3.3.2 Strap/vest 13

3.3.3 Auxiliary measurement devices 14

3.3.4 Smartphone 15

3.3.5 Games 15

3.3.6 Clinical and Psychological questionnaires 16

3.4 Extraction of user requirements 17

4 FRAILSAFE USE CASE SCENARIOS AND EVALUATION PROTOCOLS 18

4.1 Types of use cases 18

4.2 Initial use case evaluation and prioritization 19

4.3 Patient-oriented use cases 26

4.3.1 UC.PAT.01 - WWS (Wearable wellness system) - [DP] [FP] 26

4.3.2 UC.PAT.02 – Personal data visualization - [DP] [FP] 28

4.3.3 UC.PAT.03 - Adverse event – [FP] 29

4.3.4 UC.PAT.04 – Indoor activity monitoring - [DP] [FP] 32

4.3.5 UC.PAT.05 – Outdoor activity monitoring - [DP] [FP] 34

4.3.6 UC.PAT.06 – Auxiliary devices usage - [DP] [FP] 37

4.3.7 UC.PAT.07 - FORA telehealth system - [DP] [FP] 39

4.3.8 UC.PAT.08 - Virtual community platform - [FP] 41

4.3.9 UC.PAT.09 - Social media usage - [DP] [FP] 43

4.3.10 UC.PAT.10 - Physical game usage - [DP] [FP] 45
4.3.11 UC.PAT.11 - Cognitive game usage - [DP] [FP] 48
4.4 Family-oriented use cases 51
4.4.1 UC.FAM.01 – Older person data visualization - [DP] [FP] 51
4.4.2 UC.FAM.02 – Adverse event – [FP] 52
4.4.3 UC.FAM.03 – Virtual community platform - [FP] 54
4.5 Healthcare professional-oriented use cases 57
4.5.1 UC.CLI.01 - WWS (Wearable wellness system) preparation - [DP] [FP] 57
4.5.2 UC.CLI.02 – Older person data visualization - [DP] [FP] 58
4.5.3 UC.CLI.03 – Adverse event – [FP] 60
4.5.4 UC.CLI.04 – Clinician suggestions - [DP] [FP] 62
4.5.5 UC.CLI.05 – Virtual community platform - [FP] 64
4.5.6 UC.CLI.06 – Indoor localization preparation - [DP] [FP] 65
4.5.7 UC.CLI.07 – Outdoor localization preparation - [DP] [FP] 67
4.5.8 UC.CLI.08 – Dynamometer - [DP] [FP] 68
4.5.9 UC.CLI.09 - FORA telehealth system - [DP] [FP] 71
4.5.10 UC.CLI.10 - Cognitive game preparation - [DP] [FP] 73
4.5.11 UC.CLI.11 – Clinical web platform - [DP] [FP] 75
4.6 Researcher-oriented use cases 78
4.6.1 UC.RES.01 – Database browsing - [DP] [FP] 78
4.6.2 UC.RES.02 – Database querying - [DP] [FP] 79
4.6.3 UC.RES.03 – Visual analytics - [DP] [FP] 81
4.6.4 UC.RES.04 – Hypothesis testing - [DP] [FP] 83
4.7 FrailSafe evaluation protocols 85
4.7.1 Ethics 86
4.7.2 Data management 86
4.7.3 Patient safety 86
5 FRAILSAFE USER CENTERED DESIGN METHODOLOGY 87
5.1 Introduction 87
5.2 Methods for User Centered Design 87
5.2.1 Methods for user feedback assessment 87
5.2.2 Methods for user-assisted design 88
5.2.3 Methods for user-assisted implementation 89
5.3 UCD methodology for FrailSafe 89
5.3.1 UCD plan for the sensor network and wearable sensing system 91
5.3.2 UCD plan for the personalized information visualization and DSS 92
5.3.3 UCD plan for the game suite 93

5.3.4 UCD plan for the integrated FrailSafe system 94
6 CONCLUSIONS 95
REFERENCES 96
A. QUESTIONNAIRES 97

TABLE OF FIGURES

Figure 1: The overal flow of procedures followed in tasks T1.2 and T1.3. 1
Figure 2: Sample photos from the conduction of the focus groups. 10
Figure 3: Percentages of different types of participants in the feedback collection procedure. 11
Figure 4: Feedback regarding the project as a whole. 12
Figure 5: Feedback about FrailSafe tools usage. 13
Figure 6: Feedback about usage of each FrailSafe tool. 13
Figure 7: Feedback regarding the strap/vest usage. 14
Figure 8: Feedback regarding the blood pressure tool usage. 14
Figure 9: Feedback regarding the dynamometer usage. 15
Figure 10: Feedback regarding the smartphone usage. 15
Figure 11: Feedback regarding the games usage. 16
Figure 12: Screenshot of the online use case evaluation and prioritization form. 20
Figure 13: Hierarchy of requirement types. 90

LIST OF TABLES

Table 1: FrailSafe focus group demographics. 9
Table 2: Use case description template. 18
Table 3: Prioritization of the initial use cases. 21

LIST OF ABBREVIATIONS AND ACRONYMS

(*in alphabetic order*)

AR	Augmented Reality
BP	Blood Pressure
DSS	Decision Support System
ECG	Electrocardiogram
EU	European Union
FTP	File Transfer Protocol
GPS	Global Positioning System
GSMA	Groupe Speciale Mobile (GSM) Association
ICT	Information and Communication Technology
IMU	Inertial Measurement Unit
IT	Information Technology
LED	Light-Emitting Diode
mHealth	Mobile Health
PC	Personal Computer
PDA	Personal Digital Assistant
UCD	User Centered Design
UML	Unified Modeling Language
VPM	Virtual Patient Model
WBAN	Wireless Body Area Network
WWBS	Wearable WBAN System
WWS	Wearable Wellness System

1 INTRODUCTION

The definition of the user needs and requirements is one of the most important first steps in the design of a large-scale project. The aim of this deliverable is to report the progress conducted towards gathering information about the end-user needs and how this knowledge has led to the definition of the specific user scenarios on which the rest of the system design is based. Moreover, this deliverable reports the methodologies that will be followed in order to ensure that the end-user needs remain at the center throughout the design and implementation phases of the project.

The overall flow of goals and procedures followed in the course of tasks T1.2 and T1.3, which are related to this deliverable, is depicted in Figure 1. First, the end-user groups are identified. Then, feedback acquisition procedures are employed in order to collect feedback from representative users. The analysis of this feedback leads to the identification of the user requirements, which is the basis for the definition of specific use cases for the system. As a final step, the use cases are used in order to create protocols for the evaluation of the final integrated system and its components.

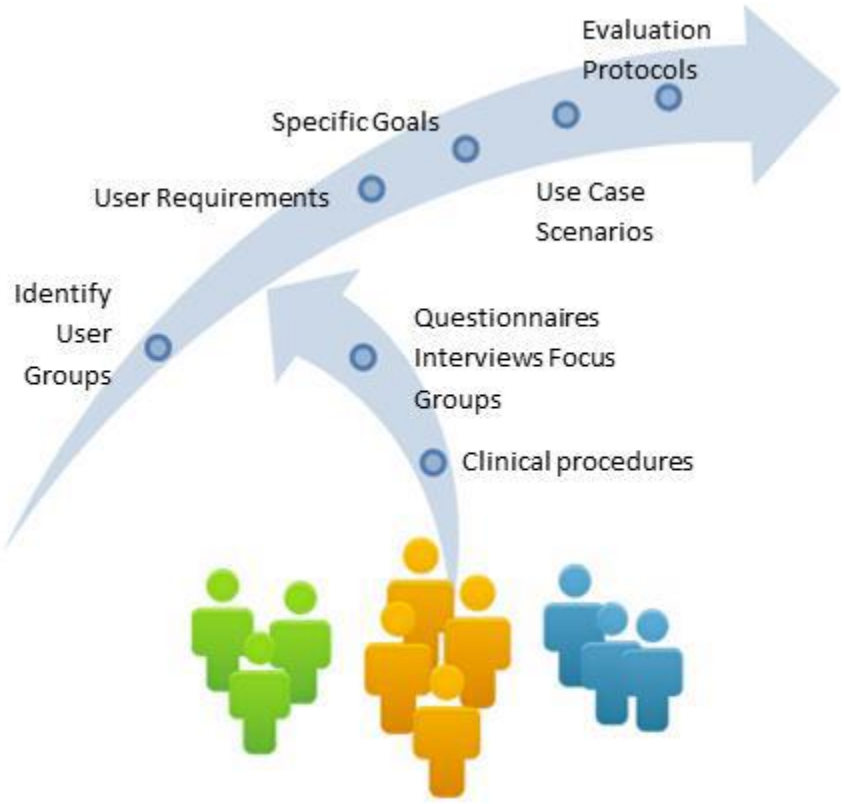


Figure 1: The overal flow of procedures followed in tasks T1.2 and T1.3.

After the current introduction, the deliverable is organized as follows:

- Chapter 2 contains a short description of the positioning of this deliverable within the context of the FrailSafe project objectives. After an introduction to the problem of frailty and on the related issues that older people and clinicians are faced with, the importance of user requirements elicitation is highlighted with relation to the specific project objectives.
- Chapter 3 describes the procedure followed for the collection of the user requirements regarding all parts of the system. First, the end-user groups are

identified. Then, the procedure followed for feedback collection is presented, involving surveys, interviews and focus groups. Finally, an analysis of the collected data is presented, showing the requirements and expectations that end-users have from the FrailSafe system.

- After the elicitation of the user requirements, Chapter 4 contains a detailed description of the various use cases and scenarios, from the viewpoints of the various identified user groups. There are four categories of use cases: older-person-oriented, family-oriented, clinician-oriented and researcher-oriented. Each use case is described in detail, accompanied with diagrams depicting the various steps of the use case flow.
- Chapter 5 describes the User Centered Design (UCD) methodology that will be followed throughout the project. The chapter begins with an overview of existing and widely used methodologies for considering the user needs in the design and implementation phases of a project. This overview is followed by the specific UCD plan that will be followed within FrailSafe.
- Finally, Chapter 6 concludes the deliverable, summarizing its contents.

2 POSITIONING OF THE DELIVERABLE IN FRAILSAFE OBJECTIVES

In order to clarify the importance of a deliverable about user requirements and user-centered design methodologies, a brief introduction to the condition of frailty and the obstacles it poses to both older persons themselves and clinicians is presented, followed by how user requirement elicitation and user-centered design fit within the objectives of the FrailSafe project.

2.1 Frailty

Frailty is a medical syndrome with multiple causes and contributors that is characterized by diminished strength, endurance, and reduced physiologic function that increases an individual's vulnerability for developing increased dependency and/or death [1]. Frailty is characterized by multiple pathologies: weight loss, and/or fatigue, weakness, low activity, slow motor performance, and balance and gait abnormalities. There is also a potential cognitive component [2]. Frailty makes elderly more vulnerable to stressors and has major health care implications, such as increased risk of incident falls, delirium, worsening of mobility, disability, hospitalization, institutionalization, and mortality [3][4][5], which eventually increase the burden to cares and costs to the society.

A single operational definition of frailty has not been agreed so far, as experts in a recent consensus conference have failed to agree [1]. The lack of standardized definition of frailty causes heterogeneity in studies. Frailty as a syndrome is characterized by a cluster of symptoms and signs that can be grouped in a physical, cognitive, functional, and social domain. Of these domains, the physical frailty phenotype is more studied and described by weight loss and sarcopenia, weakness with low grip strength, exhaustion or poor endurance, slow motor performance (e.g., slow walking speed, decreased balance) and low physical activity, as a marker of low energy expenditure [6]. The cumulative deficit model provides an alternative operational definition of frailty. It is based on a comprehensive geriatric assessment and takes into account ninety-two baseline parameters of symptoms, signs, abnormal laboratory values, disease states and disabilities, referred as deficits, to define frailty [7].

Since frailty is a condition whose symptoms develop during a large period of time and whose effects affect the everyday life of the older persons. Providing means to self-monitor the health condition, in physical, physiological and cognitive terms, would allow the older persons and the caregivers to have a clearer view of the progress of frailty and be more ready, through training exercises, to halt its symptoms. Moreover, an automatic system of personalized real-time data collection, supported with online and offline data analysis, assists significantly the healthcare professional. Since the goals of the FrailSafe system are towards the assistance of the older persons and the healthcare professionals, the specific needs of these end-users from such a system are very relevant to the project's goals. Involving the end users in the process of design and implementation of FrailSafe is important in order to achieve these goals.

2.2 Importance of user involvement for the fulfilment of the FrailSafe objectives

In order to further clarify the importance of user involvement in fulfilling the goals of FrailSafe, the following subsections present how user involvement is related to the fulfilment of a number of FrailSafe objectives, as they have been presented in the project's description.

2.2.1 Medical objectives

Objective	Importance of user involvement
MO1: Better understand frailty and its relation to co-morbidities.	Users will be evaluated for all aspects in parallel (cognitive, nutrition, psychological, social, medical etc) and co-morbidities will be investigated.
MO2: Develop quantitative and qualitative measures to define frailty.	Involvement of clinician end-users is important at various phases during the project's evaluation, in order to refine the parameters used and the processes involved to define frailty measures.
MO3: Use these measures to predict short and long-term outcome.	The involvement of clinician users is important in order to ensure that the predicted outcomes are accurate.
MO4: Develop real life tools for the assessment of physiological reserve and external challenges.	Their feedback when using the tools is very important for improving and/or changing the tools.
MO5: Provide a model sensitive to change in order that will facilitate the testing of pharmaceutical and non-pharmaceutical interventions, which will be designed to delay, arrest or even reverse the transition to frailty, can be tested.	The involvement of clinicians in the design of the data models and intervention services is very important, in order to ensure that accuracy, safety and ethics are taken into account.
MO6: Create "prevent-frailty" evidence based recommendations for older people regarding activities of daily living, lifestyle, nutrition, etc. to strengthen the motor, cognitive, and other "anti-frailty" activities through the delivery of personalised treatment programmes, games, monitoring alerts, guidance and education and estimate the influence of these interventions.	Through the clinical assessment and the application of the frailsafe system we can obtain useful and new information regarding frailty and co-morbidities. We can investigate direct effects for frailty; which tools and aspects are linked to frailty and thus provide prevention and intervention recommendations.
MO7: Achieve all with a safe and acceptable to older people system.	The frailsafe tools will be tested both for their safety and acceptability and by the feedback of the users we can amend and improve them to the final product which will be safe and acceptable.

2.2.2 Technological objectives

Objective	Importance of user involvement
TO1: Design and development of hardware components (ambient and wearable sensors, body node coordinator (e.g., smart phone) optimised in terms of	Older person and clinician feedback when using the tools is very important for improving and/or changing the tools, both in terms of functionality and in terms of

ergonomics, user-friendliness compactness, unobtrusiveness and energy consumption that can be used indoors and outdoors providing functionalities for effective yet simple and economical personalized monitoring of the individual patient's condition for purposes of detecting/alerting/averting of frailty events, merged to an integrated system, explicitly taking into account security and privacy issues.	ensuring safety and usability.
TO2: Design and development of efficient signal processing algorithms for low level processing including signal enhancement, activity classification, energy expenditure, and behavioural monitoring.	User feedback regarding the tool usage is very important for improving and/or changing the tools.
TO3: Development of a self-adaptive virtual patient model offering optimal services for managing frailty ranging from critical situation management, facilitating social integration to day-to-day self-management and health preservation based on a personalized patient profile.	The involvement of clinicians in the process of designing and fine-tuning the parameters of the Virtual Patient Model is important, in order to ensure that the included parameters are useful and relevant.
TO4: Development of a generic monitoring and management infrastructure on which modular services and patient-specific applications will be built.	Involvement of older persons, clinicians, as well as commercial organizations and technology developers will assist in achieving a robust and acceptable monitoring and management system.
TO5: Development of novel methods for the offline management, fusion and analysis of multimodal and advanced technology data from social, behavioural, cognitive and physical activities of frail older people and application of these methods to manage and analyze the large amounts of data collected leading to integrative interpretation and better understanding of frailty, introduction of new quantitative frailty biomarkers as well as frailty metrics, correlation of co-morbidities and frailty, advanced decision making capabilities (DSS) assisting diagnosis by medical professionals.	The involvement of clinicians and researchers in the field of frailty is important, in order to ensure that the developed data analysis, visualization and decision support systems provide accurate and comprehensive information and are useful and usable.
TO6: Development of real-time data management and data mining methods effectively making decision assessing frailty levels, detecting frailty risks and triggering alarms in case of emergency situations (e.g., fall, loss of orientation, incoherent utterances or suicidal	The involvement of clinicians and older persons is important, in order to effectively evaluate the developed algorithms of real-time detection and decision making, and ensure that safety and ethics requirements are fulfilled.

manifestations in electronic written text10) based on minimal processing of real-time multi-parametric streaming data and economical personalized monitoring guided by a minimal number of sensors and parameters (FrailSafe prediction engine and Risk Factor Evaluation).	
TO7: Investigation of processing time, storage and communication trade-offs for real-time analysis at the WBAN or the phone/PDA and use of data reduction and summarization techniques for reducing raw streaming data to secondary or tertiary parameters. Effectively use virtual patient models and results from the offline data mining of multi-parametric data to make real-time analysis more efficient and targeted.	Resolving performance issues regarding the communication among the various components can be significantly assisted through the conduction of real-world usage scenarios, involving actual older person, clinician and researcher end-users.
TO8: Development of a dynamically synthesized, personalized and highly innovative AR game consisting of different scenarios that will take place in the real world than in a virtual one that measures parameters of behavioural, cognitive and physical domain while implementing various intervention strategies.	Older person and clinician feedback regarding using the games is very important for improving and/or changing them.
TO9: Extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards.	The involvement of older people, clinician and researcher end-users is very important in order to ensure that the whole FrailSafe system performs correctly and following safety, ethics and usability user requirements.

3 FRAILSAFE USER REQUIREMENTS

In this section, the procedure followed for the acquisition of the user needs and requirements is described. The user requirements assessment procedure followed in FrailSafe consists of the following steps:

1. Identification of the target user groups
2. Design of the assessment campaigns, with the formation of specific focus groups and the preparation of questionnaires.
3. Conduction of the focus groups and surveys and collection of feedback.
4. Analysis of the collected data, e.g. using histograms, pie charts, etc.
5. Extraction of user requirements.

These steps are presented in detail in the following sections.

3.1 FrailSafe target user groups

The target user groups that will benefit from the outcomes of the FrailSafe system and the needs of which guide the design of the system, can be divided in the following categories:

- **Older persons**. This group is the core user group of FrailSafe. The needs of the older persons with regard to frailty, i.e. the need to be able to monitor one's condition and the need for methods to prevent or decelerate the effects of frailty are the core objectives of the whole FrailSafe project. Frailsafe aims to provide means for constant monitoring of physiological, physical, cognitive, behavioural and social parameters of the older persons, through a network of sensors (either wearable or placed in the older person's environment), measurement devices, software applications and games. The project also aims at providing tools for the older persons to have an overview of their health status and to have access to personalized lifestyle suggestions, assisting them in coping with frailty.
- **Families of older persons**. The families and relatives of the older people are usually the ones with a constant direct contact with the older people. Relatives need to have ways to monitor the health condition of the older persons and ways to receive notifications and alerts regarding the older persons, in cases of emergency, while they are not around. FrailSafe aims at covering both these needs by providing mobile applications for remote monitoring of the clinical and behavioural characteristics of the older persons, as well as methods for automatic detection of unfortunate events, such as falls, which trigger notifications and alerts being sent to the relatives.
- **Medical healthcare professionals**. This group of users is the one responsible for the medical monitoring of the older people and their treatment. Similar to families, medical professionals need ways to monitor the older persons and to receive notifications in cases of emergency. Moreover, they need ways to view the patients' progress over time, make decisions regarding their treatment and provide recommendations about lifestyle changes. Through its mechanisms for clinical and behavioural monitoring and automatic detection of events, FrailSafe aims at fulfilling the corresponding needs of the medical professionals. Regarding the decision making-related needs, FrailSafe aims to provide the medical professionals with information visualization tools and a decision support system, in order to assist them in examining the older person's data and take decisions about possible treatments and suggestions.
- **Researchers in the field of frailty**. This group consists of users willing to use the data collected within the project, as well as the available analysis algorithms, in order to do research regarding frailty and the effects of various clinical and behavioural parameters, as well as of various treatments, on the

development of frailty indications. The users of this group need tools to assist them in examining and analysing the data of large numbers of older persons, in order to identify useful patterns. FrailSafe aims to assist these users by providing database querying mechanisms, automatic data analysis and visual analytics and hypothesis testing tools.

3.2 Design of the requirements assessment campaigns

In order to fulfil the goal of user-centered design, the opinions of representatives of the target user groups need to be collected, regarding various parts of the system. The process of recruiting end users and collecting their feedback consisted of various steps, which are presented in the following sections.

3.2.1 Initiation

The first step was the identification of the potential partner organizations that can provide access to a wide range of participants in the older person user group. The clinical partners used the campaigns available, which were the questionnaire, focus groups, surveys and interviews to obtain feedback for the program and for each frailsafe tool separately. Also, medical professionals were identified and the relatives of the users, which were sent an email. Feedback regarding the program and the frailsafe tools were received and amendments were made. For example, users and clinicians noticed that it is very difficult to play the games on their own on the tablet as every time they had to login with their unique codes in order to enter the game. Therefore, a suggestion was made to technical partners to change this so that the users enter their unique code only once and then be able to play the game throughout the days.

3.2.2 Construction of questionnaires

A first draft of a questionnaire was created and given to clinical partners and users for feedback. Both clinical partners and users suggested adding less questions and mostly closed-ended questions in order to be easier for the users to complete the questionnaire. However, in order to obtain quantitative data, we kept at least one open-ended question for each tool asking for their feedback for improvement and/or changes for each tool. Also, during the administration of the questionnaires to the users, the users were more willing to discuss the issues than completing the questionnaire, and so some information was received through face to face interviews. Therefore, a second questionnaire was created as a final tool for focus groups. The final questionnaire used can be found in Appendix A.

3.2.3 Development of focus groups

The first step was to identify possible focus groups. Criteria for a focus group is 70+ aged both female and both and users with a variety of frailty level in order to have a smooth allocation. For example, day care centers have mostly active users. The purpose of the focus groups is to collect feedback, to inform users for the frailsafe program and also recruit participants for the program.

3.3 Feedback collection and analysis

Four focus groups have been formed, organized by MATERIA in Cyprus. In total, 102 older persons participated, aged between 65 and 94 years. The focus groups consisted mostly of male participants (75 male, 27 female). The detailed demographics of the focus groups that have been recruited for the purposes of collecting end-user feedback are described in Table 1. Figure 2 contains some representative photos from the focus groups.

Table 1: FrailSafe focus group demographics.

ID	Date	Location	# members	Gender	Age
1	30/3/2016	Lakatamia Senior Day Club, Nicosia, Cyprus	27	18 male, 9 female	70-94
2	15/5/2016	MATERIA Premises, Nicosia, Cyprus	40	22 male, 18 female	70-92
3	5/9/2016	Chalkanor Community Center, Nicosia, Cyprus	20	20 male	68-88
4	22/11/2016	Adonis Club, Nicosia, Cyprus	15	15 male	65-85

Figure 2: Sample photos from the conduction of the focus groups.

During the focus groups, the FrailSafe project was presented to the participants, and interviews were conducted with them, in order to collect their opinion regarding the project as a whole, as well as its separate components. The feedback collected was mostly positive, which is a significant motivation for further development according to the older person needs. Some of the participants were already participating in FrailSafe, using various components, such as the games, so there was the chance to collect more specific feedback.

None of the participants withdrew during the focus groups, interviews and questionnaire sessions, even though they were explicitly and emphatically told that they can stop anytime without needing to explain their withdrawal.

Many older persons were escorted by their children/spouse/partner in the focus groups, so there was a chance to interview them as well (38 people). We also e-mailed a few

relatives of clients in the community. The feedback from the older persons' families was also positive. The most prominent reason they reported positive feelings was in relation to the predictive nature of the tool. Most of them are worried about their loved ones when they are not near, and they feel that predictive treatments will be a way to reduce their real risk of becoming frail, or more frail than they currently are.

Members of MATERIA GROUP were also recruited in separate focus groups in order to collect feedback from healthcare experts. A presentation (and e-mail to those who were absent) was made to the inter-disciplinary team of MATERIA GROUP, which consists of 45 health care professionals working in Medicine, Nursing, Physiotherapy, Speech-Language Therapy, Social Work, Clinical and Cognitive Psychology and Nutrition. A discussion followed where feedback was overall positive and interest in the development of the project was strong. Words like "innovative", "useful" and "necessary" were mentioned. Interestingly, different professionals were interested in different components of FrailSafe, according to their discipline (physio – balance and mobility risk assessment aspects, cognitive people with the gaming aspects etc). All were willing to give feedback during the development of the FrailSafe system.

Figure 3 depicts the percentages of the different types of participants in the above groups, who were recruited for the user requirement feedback procedure. More details about the feedback collected for the project as a whole, as well as for various components, are presented in the following sections.

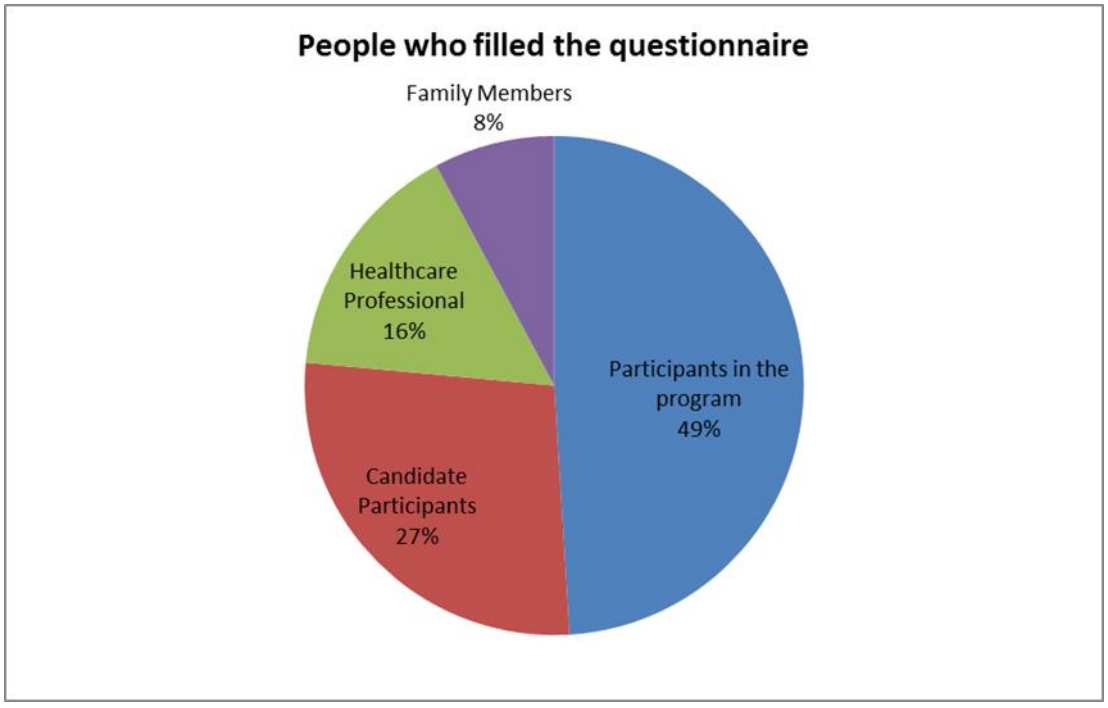


Figure 3: Percentages of different types of participants in the feedback collection procedure.

3.3.1 Project as a whole

All participants, from all categories, considered the project as important. 92% of the older person participants generally reported positive feelings towards the concept of Frailsafe, and referred other older friends/relatives for participating. They agreed that people aged 70+ would benefit from participating in Frailsafe, since it relates to their own health. Participants especially liked the fact that the health professionals will visit them at home. They felt it was attractive that they will receive individualised lifestyle

and health advice via the Frailsafe system, and they are not just giving feedback, but also receiving in the end.

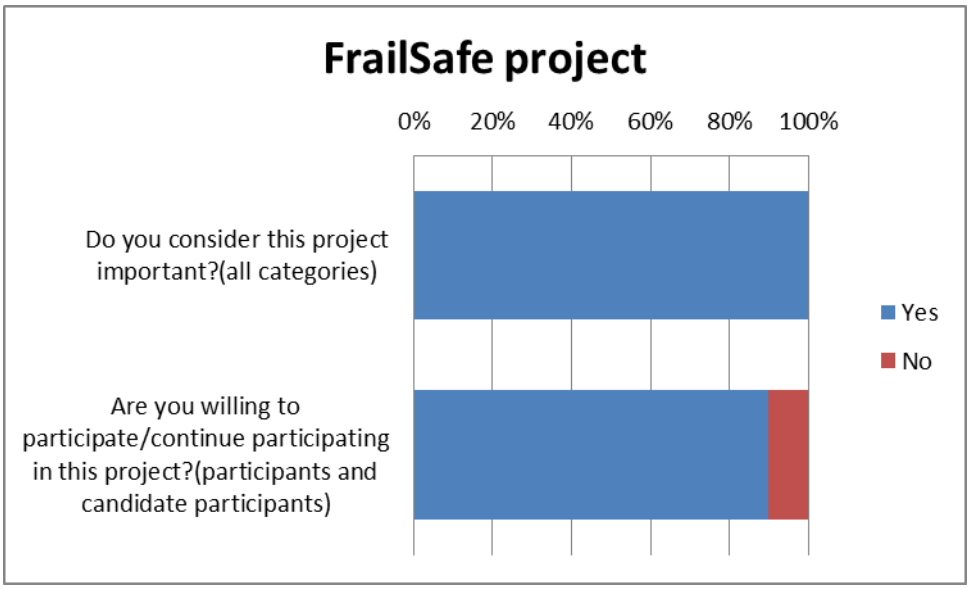


Figure 4: Feedback regarding the project as a whole.

Participants reported willing to participate in the frail safe program, and about 70% enrolled after the focus groups. Furthermore, 89% of participants were willing to participate in a follow up feedback session, even through the telephone.

On the other hand, one participant was hesitating to participate, as he had doubts that the program would really be for free. Such comments suggest that it should be emphasized that the older persons' voluntary participation is free.

Most of the older persons already participating in FrailSafe reported that they have used the tools of FrailSafe, as depicted in Figure 5. As depicted in detail in Figure 6, from the measurement devices, the blood pressure tool and the dynamometer were mostly used. Regarding the wearable sensors, a belt has been used, instead of the vest, in this early stage of feedback acquisition. Several participants also used the tablet and smartphone and have played a game on the tablet.

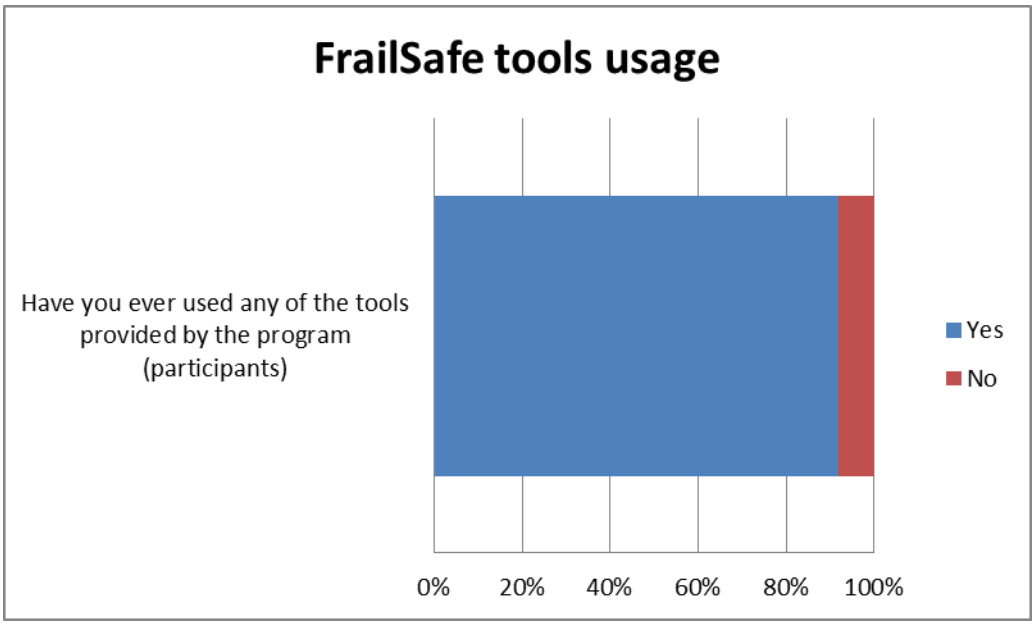


Figure 5: Feedback about FrailSafe tools usage.

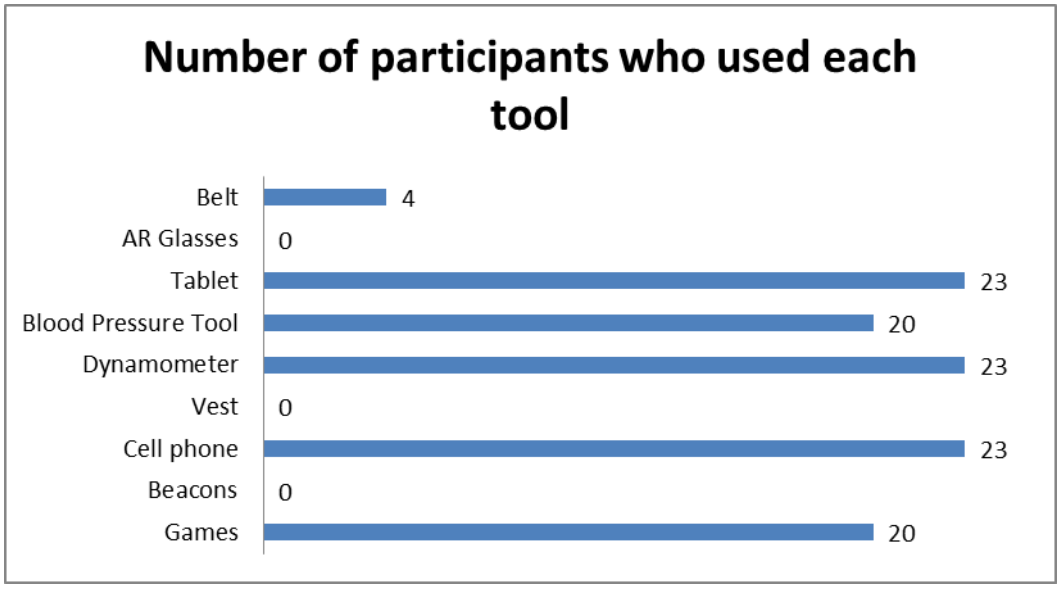


Figure 6: Feedback about usage of each FrailSafe tool.

3.3.2 Strap/vest

Regarding the wearable sensors, most participants reported a willingness to wear a strap or vest for a few hours a day, although wearing it constantly was not desired. Of those who have already used the straps, a few technical difficulties were reported. Of those that refuse to wear the strap or vest, there was an occasion that the refusal was due to allergies and thus the participant not being sure of the product's safety.

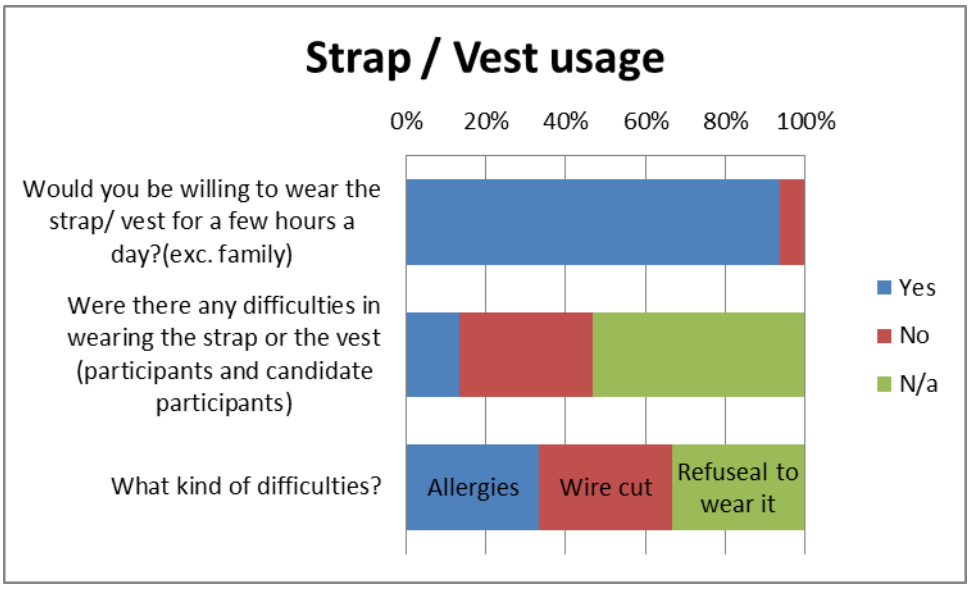


Figure 7: Feedback regarding the strap/vest usage.

3.3.3 Auxiliary measurement devices

Several participants tried using the blood pressure tool and the dynamometer for measuring blood pressure and strength, respectively. Regarding the blood pressure tool, as depicted in Figure 8, none of the participants that tried it reported any difficulties while using the device. Furthermore, most of the participants, both older persons and healthcare professionals, reported that the older persons would be able to incorporate the usage of the device in their daily life.

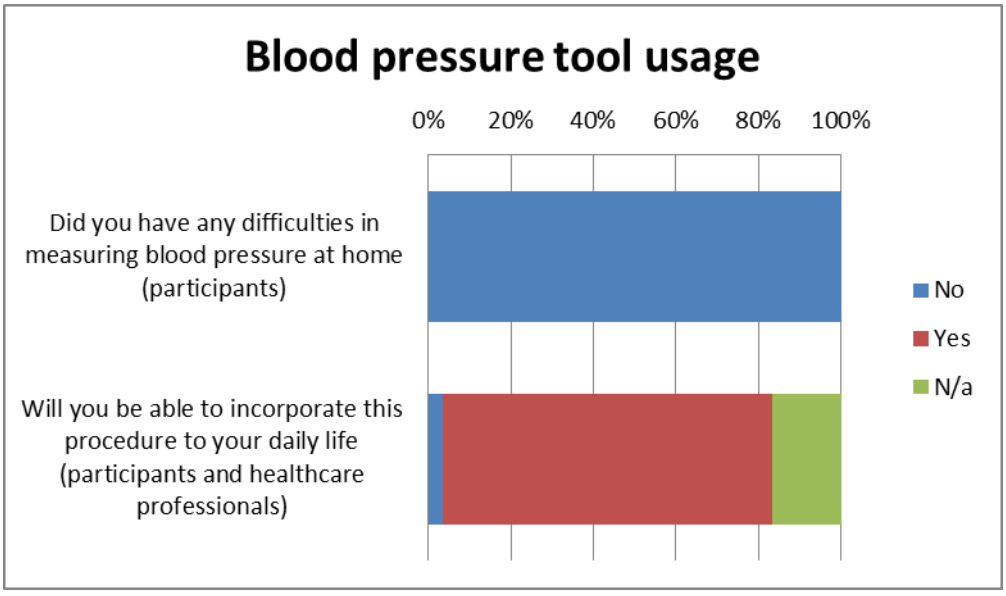


Figure 8: Feedback regarding the blood pressure tool usage.

Similar results were obtained for the use of the dynamometer, where, as shown in Figure 9, no participant reported having difficulties while using the device, while they would all be able to use the dynamometer in their daily life, without any assistance.

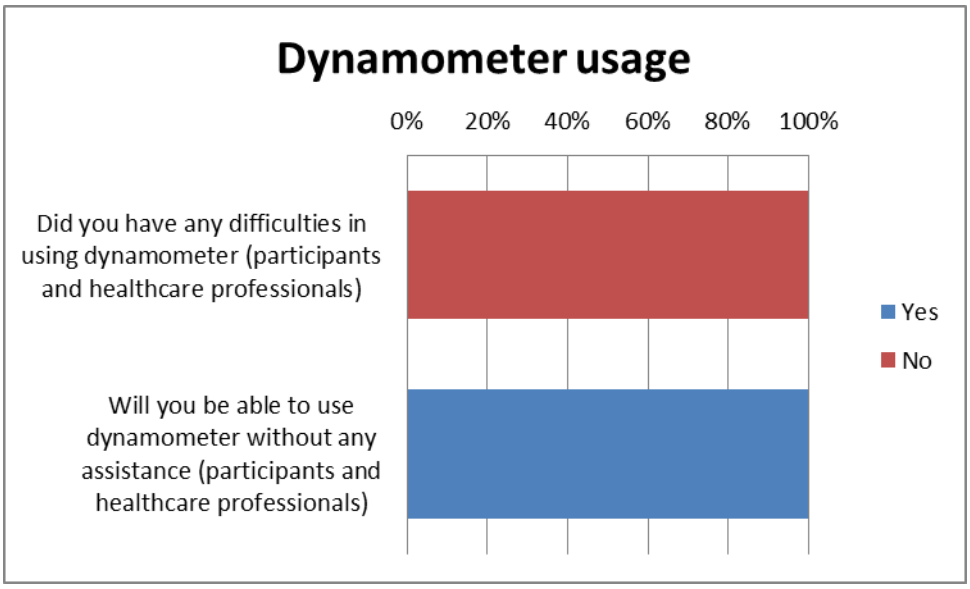


Figure 9: Feedback regarding the dynamometer usage.

3.3.4 Smartphone

Those participants that used the smartphone, both older persons and healthcare professionals, did not report any difficulty while using it, as depicted in Figure 10. Furthermore, both older persons and healthcare professionals reported that an older person would be able to use a smartphone in his/her daily life without any assistance.

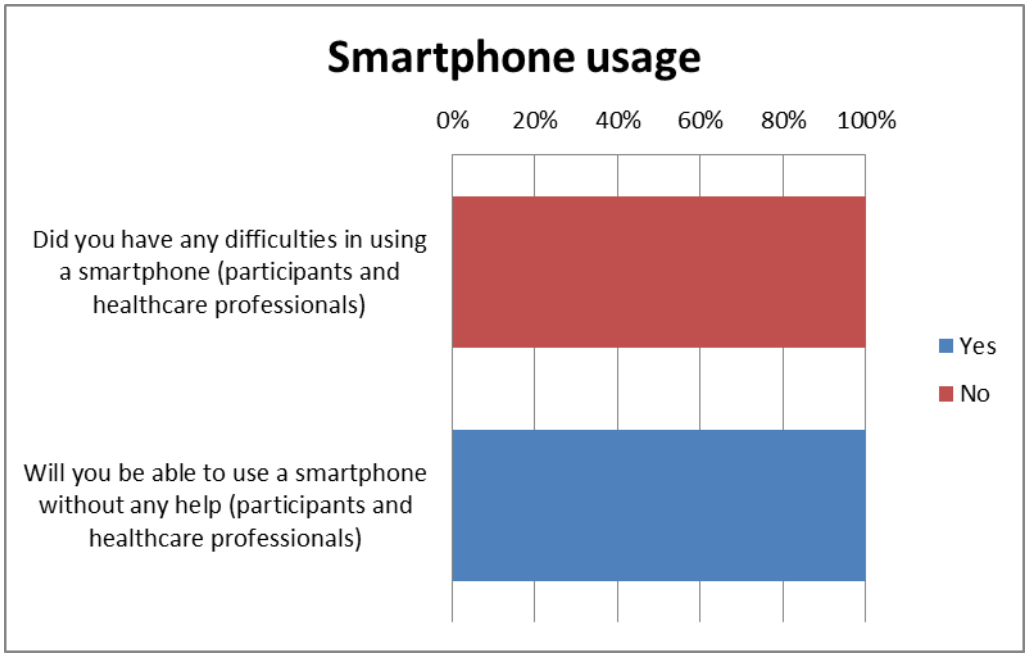


Figure 10: Feedback regarding the smartphone usage.

3.3.5 Games

In this early stage of feedback acquisition, the “Supermarket” cognitive game was presented to and tried by the participants. Participants not familiar with the usage of IT devices were skeptical at first in trying the game. They became more positive after

trying it and reported that was easier than they initially thought. However, they still located difficulties which were reported to the IT partners. As Figure 11 depicts, these difficulties were mostly related to the login procedure, which they found to be complex and tiring. Some participants also reported difficulties regarding their orientation in the game and the tablet usage in general. Due to these reported difficulties, most participants considered that they would not be able to use the game without any assistance.

A few of the participants (mostly non-frails and highly active) said that they would prefer to socialize and go out of the house than play a game. Such comments make it necessary to improve the games so that they are more attractive and enjoyable, employing physical activity as well as cognitive.

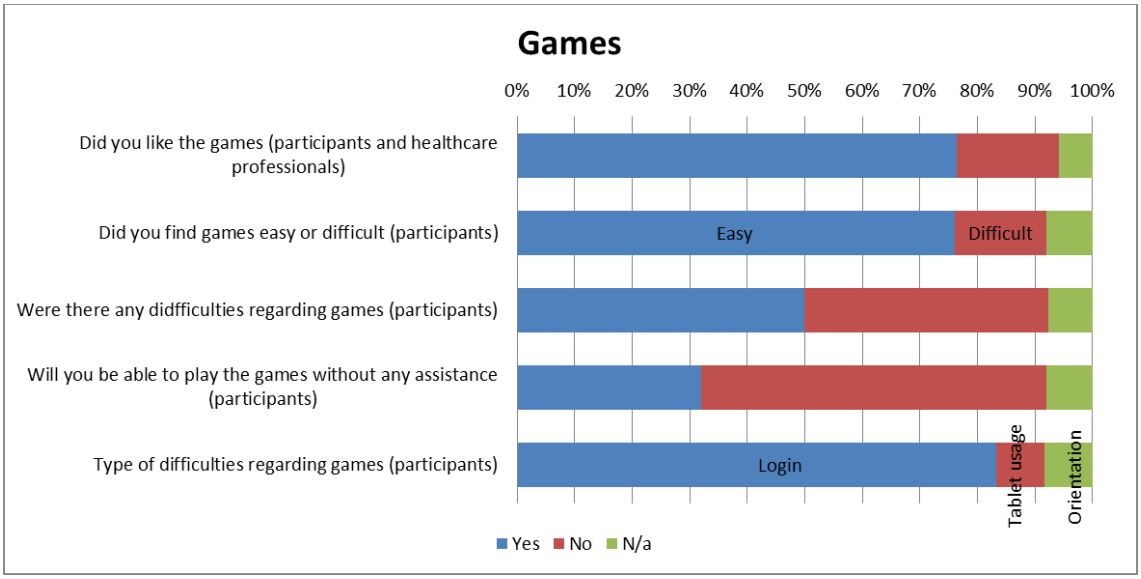


Figure 11: Feedback regarding the games usage.

3.3.6 Clinical and Psychological questionnaires

Questionnaires regarding clinical and psychological characteristics of the users will be employed throughout the course of the project, for data collection. These questionnaires were presented and used by the participants of the focus groups.

Regarding the clinical assessment questionnaire, three of the participants were nervous before starting the clinical questionnaire because they thought the questionnaires would test their general knowledge. Participants also had difficulties in deciding a number to rate their scales for pain, anxiety and quality of life.

Regarding the psychological questionnaires, the big five questionnaire was the least favorite, as participants found it long and had difficulties understanding the scale. One of the favorite questionnaires was the written text. Participants were eager to write after so many years and felt like they were at school. However, some were feeling nervous for the spelling and grammar, especially those with few years of formal schooling.

In a different aspect, one participant asked for the confidentiality of the written texts, because he wanted to write something very personal. Two more participants needed more info on the confidentiality policy. Such comments suggest that there is a need for clarifications regarding the confidentiality policy, during the clinical and psychological assessment.

3.4 Extraction of user requirements

Based on the above analysis of end-user feedback during this first year, the following priorities and user needs have been identified, which can be addressed by the FrailSafe system:

- Need for improved understanding of frailty, its causes and ways to prevent it
- Need for individualized help from the healthcare professionals
- Need for participation by the older people and sending feedback to the healthcare personnel
- Need for enjoyable frailty-preventing activities that require physical and cognitive effort
- Need for clinical assessment methods that are easy to perform
- Need for predictive treatment functionalities in order to reduce the risk of frailty
- Need for real-time monitoring and alerts in order to reduce the anxiety of family members
- Need for sensory and measurement components that are safe to use by the older people
- Need for sensory and measurement components that are easy and comfortable to use
- Need for acceptable wearable components that are not obtrusive
- Need for frailty-related software components and games that are easy to use and learn
- Need for hardware interaction devices that are easy to use
- Need for extensive data collection for research

The FrailSafe consortium believes that all the above user needs can be addressed by the final FrailSafe system. FrailSafe aims use an extensive collection of data from field trials with older people using unobtrusive sensor networks, in order to study frailty and understand is causes and methods of prevention. The collected data will be used to construct personalized models of each involved older person, in order to offer personalized monitoring and suggestions of an older person. The sensor network is aimed to be used for real-time monitoring, producing alerts when something unusual is detected. Older person participation for data collection and rehabilitation procedures will be accomplished through clinical measurements and physical/cognitive exercises and games, which are meant to be enjoyable.

4 FRAILSAFE USE CASE SCENARIOS AND EVALUATION PROTOCOLS

In this section, the use cases of the FrailSafe system are detailed, viewed from the perspective of the various considered end-user groups. The steps of each use case scenario are described in detail. An indicative set of these use cases will be the basis for the definition of the pilot scenarios to be executed during the evaluation phase of the project. It should be notet that these scenarios may be subject to changes due to modifications or clarificatins of the user requirements, as the project proceeds. The indicative use case scenarios to be used for the pilot studies will be finalized in deliverable D7.1.

4.1 Types of use cases

In FrailSafe, the following types of use cases will be considered:

- **Patient-oriented use cases**, e.g. “The patient performs daily actions. The FrailSafe vest collects information and sends them to the data collection module…”
- **Family-oriented use cases**, e.g. “The family member receives an alert in his/her mobile phone indicating that the older person had a loss of balance.”
- **Healthcare professional-oriented**, e.g. “The doctor logs in the FrailSafe system and selects the tool for supervision of patients of his/her responsibility. The doctor selects a specific patient and choses to add/edit the prescribed action plan…”
- **Researcher-oriented**, e.g. “The researcher loads the data that have been collected for a specific patient using the data analysis and visualization tool and selects a visualization method…”

The use cases for each of the above categories are presented in detail in the following sections. Each use case is described using the template presented in Table 2.

Table 2: Use case description template.

Generic Description	
Use Case Name	In this section enter a Use Case name, which uniquely identifies the use case (e.g. unique identifier), having an achievable goal.
Version	To inform the user the stage a use case has reached.
Authors	Who created and who documented the Use Case.
Last Update	Shall include all previous updates made to the actual Use Case.
Brief Description	Please describe the series of steps for the defined use case in a clear concise manner. Include in the description of what the FrailSafe system shall do for the involved actor to achieve a particular goal.
Assumptions & Pre-Conditions	This part may describe the conditions that generally does not change during the execution and should be true to successfully terminate the use case. Moreover, pre-conditions define all the conditions that must be met (i.e., it describes the state of the system) in order to meaningfully cause the initiation of the use case.
Goal (Successful End Condition)	The ultimate aim and end condition(-s) of the Use Case

Post-Conditions	The effects of this use case to the overall state of the system or of its core architectural elements.
Involved Actors	Who are the actors involved in the use case? The same actor may play two different roles in the same use case. An actor may be a person, a device, another system or sub-system, or time. Actors represent different roles that something outside has in its relationship with the system, functional requirements of which are being specified.
Use Case Initiation	This refers to the potential triggers or events that could initiate the use case. The type of trigger can be temporal, internal or even in respond to an external event. Normally, the initiation of a use case shall take into account also the pre-conditions, e.g. checking them prior the execution of the use case.
Main Flow	This section shall describe the typical course of events that comply with the primary scenario addressed by the use case. Basic course of events could be enough using a step-based approach.
Relationships with other Use Cases	Indicates connection with other use cases
Specific Description	
Relevance to FrailSafe WPs	Please report the relevance to the FrailSafe WPs
Privacy & Regulation restrictions	Refer to any concerns on this perspective during the execution of the use case
Environmental restrictions	Refer to any concerns on environmental restrictions during the execution of the use case
Quality of service indicators	Please refer to indicators regarding the performance, and scalability of the involved architectural elements in this use case.
References (optional)	Any reference to other reports or material helpful for the reader
Notes (optional)	
UML Sequence Diagram	Provide through a sequence diagram the logic of a complex operation, function or procedure that is implied by the use case. It contains the key architectural elements and outlines the main execution flow during the instantiation of this use case.

4.2 Initial use case evaluation and prioritization

An initial list of use cases was created early in the project and was subject to evaluation, prioritization and feedback suggestions from experts both inside and outside the FrailSafe consortium, in order to produce the final list of use cases. This initial list and the evaluation and prioritization procedure followed are presented in this section.

The prioritization was conducted using direct feedback from clinical and technical experts within the consortium, during face-to-face meetings and teleconferences. Feedback was also collected, both from inside and outside the consortium, using an online survey form[1], filled by both technical (67%) and medical (33%) experts. A screenshot of the online form is presented in Figure 12. Overall, feedback from over 30 experts was collecting, as was the target of Milestone MS2.

Figure 12: Screenshot of the online use case evaluation and prioritization form.

The prioritization of the initial use cases, as resulted from the online form and from the discussions within the consortium, is presented in Table 3. The reader should note that this list contains **intial** use cases, which may contain ideas that have been revised in the final versions. For the final use cases, please the sections following this one.

[1] https://goo.gl/forms/xnHwmADZtgDlKYW62

Table 3: Prioritization of the initial use cases.

ID	Description	Priority		
		Low	Medium	High
1	**Older person-oriented**			
1.1	The older person actively uses the **blood pressure monitor, Mobil-o-graph, dynamometer and scales**, in order to measure the blood pressure, arterial stiffness, strength and weight, respectively. The measurements are either logged automatically or manually logged by the nurse.			✓
1.2	The older person passively uses the **WWBS, mobile phone sensors and beacons** while performing regular **indoor** daily activities, in order to measure heart rate signals, respiratory signals, posture, indoor location, steps, active time, etc. The data collected are automatically logged by the system.			✓
1.3	The older person passively uses the **WWBS, mobile phone sensors and GPS** while performing regular **outdoor** daily activities, in order to measure heart rate signals, respiratory signals, posture, outdoor location, steps, social activities, etc. The data collected are automatically logged by the system.			✓
1.4	The older person plays a **game controlled by the dynamometer**, in order to indirectly perform strength-related exercises. The user performance is logged by the system.			✓
1.5	The older person wears the WWBS/IMUs and performs **exercises or games regarding the motion of the upper body**, suggested by the system. The exercises are used both to train the older person and to log his/her performance.			✓
1.6	The older persons play a dynamically synthesized serious game while wearing the **AR glasses** in order to rehabilitate their physical and cognitive state. The user performance is logged by the system.		✓	
1.7	The older persons use their **e-mail, Facebook or Twitter accounts**, etc. regularly. The system logs their messages and performs linguistic analysis, in order to identify useful social characteristics of the user.		✓	
1.8	The older person plays a **cognitive state-assessing game** (e.g. virtual supermarket) on the tablet, in order to evaluate the cognitive state of the older person. The game logs the cognitive performance of the player.			✓
1.9	The older persons use the FrailSafe **mobile front-end**			✓

	visualizations to personally monitor their health condition (clinical, physiological and behavioural parameters), their frailty-related metrics and their performance to the tasks asked by the healthcare personnel.			
1.10	The older person uses the online game FrailSafe server to **review the gaming session logs** acquired when playing the various games, and **leave messages to the clinicians**, regarding the gameplay and specific difficulties.		✓	
1.11	The older person opens the FrailSafe mobile front-end. Warnings and suggestions are presented by the front-end, regarding **long-term predicted changes to the frailty levels**, due to the current course of action and performance of the user.			✓
1.12	The older person has an unusual posture while wearing the WWBS. The mobile phone sends an **alarm about a predicted fall** to the older person.			✓
1.13	The older person uses the **Virtual Community Platform** to **exchange disease and health-related information**, as well as to promote health-related activities, fitness, daily habits and environmental safety.			✓
1.14	The older person uses the **Virtual Community Platform** to **ask questions** about diagnoses, etiology and treatment. The questions are answered by clinicians, families and other older persons.		✓	
1.15	The older person uses the **Virtual Community Platform** to **answer questions** asked by other older persons.		✓	
2	**Family-oriented**			
2.1	The family members use the FrailSafe **mobile front-end visualizations to monitor the health condition** of the older persons (clinical, physiological and behavioural parameters), their frailty-related metrics and their performance to the tasks asked by the healthcare personnel.			✓
2.2	The family members receive **alerts about risks and unusual situations** regarding the older persons, such as **falls**, through the FrailSafe mobile application.			✓
2.3	The family members **monitor the older person's social media** outgoing messages (when using the e-mail, Facebook, Twitter, etc.) and receive an **alert if something extraordinary is written** by the older person.		✓	
2.4	The family members use the **Virtual Community Platform** to **exchange disease and health-related information**, as well as to promote health-related activities, fitness, daily habits and environmental safety.		✓	

2.5	The family members use the **Virtual Community Platform** to **answer questions** posed by older persons.		✓	
3	**Medical professional/Researcher-oriented**			
3.1	The clinician uses the FrailSafe **front-end visualizations to monitor the health condition** (clinical, physical and behavioural) of the older person, as well as the frailty metrics of the older person and his/her performance at the various tasks.			✓
3.2	The clinician receives **alerts about risks and unusual situations** regarding the older persons, such as **falls**, through the FrailSafe mobile application.			✓
3.3	The clinician uses the FrailSafe front-end visualization to **identify the best methods** and actions to suggest to the patient.			✓
3.4	The clinician uses the FrailSafe system to provide **personalized feedback to the older person**, i.e. suggestions about behaviour/lifestyle/prescription changes and clinical interventions, as well as warnings and alerts for deviations.			✓
3.5	The clinician regularly uses the mobile front-end to **visually review the Virtual Patient Model and its recent updates**, in order to decide upon future actions and suggestions for the older person.			✓
3.6	The clinician uses the FrailSafe front-end to view **predictions regarding short-term and long-term future conditions** of the older person, based on his/her model. The clinician can use these predictions in his/her decision making process.			✓
3.7	The clinician uses the FrailSafe **front-end visualizations to discover common behavioural patterns** of the older person, to **correlate** them with frailty indicators and thus to identify **frailty metrics**.			✓
3.8	The clinician **monitors the older person's social media** outgoing messages (when using the e-mail, Facebook, Twitter, etc.) and receives an **alert if something extraordinary is written** by the older person.	✓		
3.9	The clinician uses the online game FrailSafe server to **review the gaming session logs** of the older persons and **view the messages** of the older persons regarding the gameplay and specific difficulties.		✓	
3.10	The clinician uses the online game FrailSafe server to update the older person profiles with **new exercises and games**.			✓

3.11	The clinician uses the **Virtual Community Platform** to **exchange disease and health-related information**, to promote health-related activities, fitness, daily habits and environmental safety, as well as to provide educational and training material.			✓
3.12	The clinician uses the **Virtual Community Platform** to **answer questions** posed by older persons.			✓
3.13	The clinician uses the **Virtual Community Platform** to **create community templates** in terms of community goal, community rules, openness, member roles, supported interaction types, supported information and content service types.			✓
3.14	The clinician uses the **Virtual Community Platform** to **evaluate the effectiveness of communities** and their impact on the health condition and personal factors of subjects.		✓	

Results of the use case evaluation procedure, based on both the above list and the discussions, include the following:

- It was decided that the medical professional/researcher actor was split into two actors. The role of the medical professional is mostly focused on monitoring individual older persons and providing personalized suggestions, while the role of the researcher is impersonal, dealing with sets of older persons and trying to explore the available data and test hypotheses. Thus, the related use cases were split into two parts, one for the medical professional and one for the researcher. The experimental phase of the project's development is characterized by the researcher's role. The role of clinician as described in the case scenario above refers to the final product' release.
- High priority should be put on use cases dealing with clinical monitoring, real-time detection of adverse events and providing suggestions to older people, while lower priority should be put on use cases dealing with social media monitoring.
- Some use cases with similar flow, such as those dealing with the information visualization for clinicians, were merged, in order to be more general and cover a wider range of possibilities.
- Regarding the final product, it was suggested that the use cases dealing with alerts be modified, so that the alerts are not directly sent to clinicians or families. Since clinicians or families cannot be available or able to react at all times, in case the older person experiences an adverse event, such as a loss of balance, it was suggested that the alerts be instead directed to a customer service, a call center, which is available in a 24/7 basis. It is then the customer service's responsibility to decide on whether a clinician or a family member is notified, or to assign a caregiver to visit the older person's home to inspect the event. Direct alerts towards the clinicians or family members will only be sent if the automatic decision support system detects that the event is rather severe.

Based on the feedback acquired during use case evaluation, the final list of uses cases is presented in detail in the following sections. In order to distinguish between the use cases that will be considered during the system's development and those that are only applicable for the final FrailSafe product, the following notation is introduced:

- **[DP]** : Development product, i.e. use cases that will be considered during the system development and training,
- **[FP]** : Final product, i.e. use case that will be considered for the final product.

4.3 Patient-oriented use cases

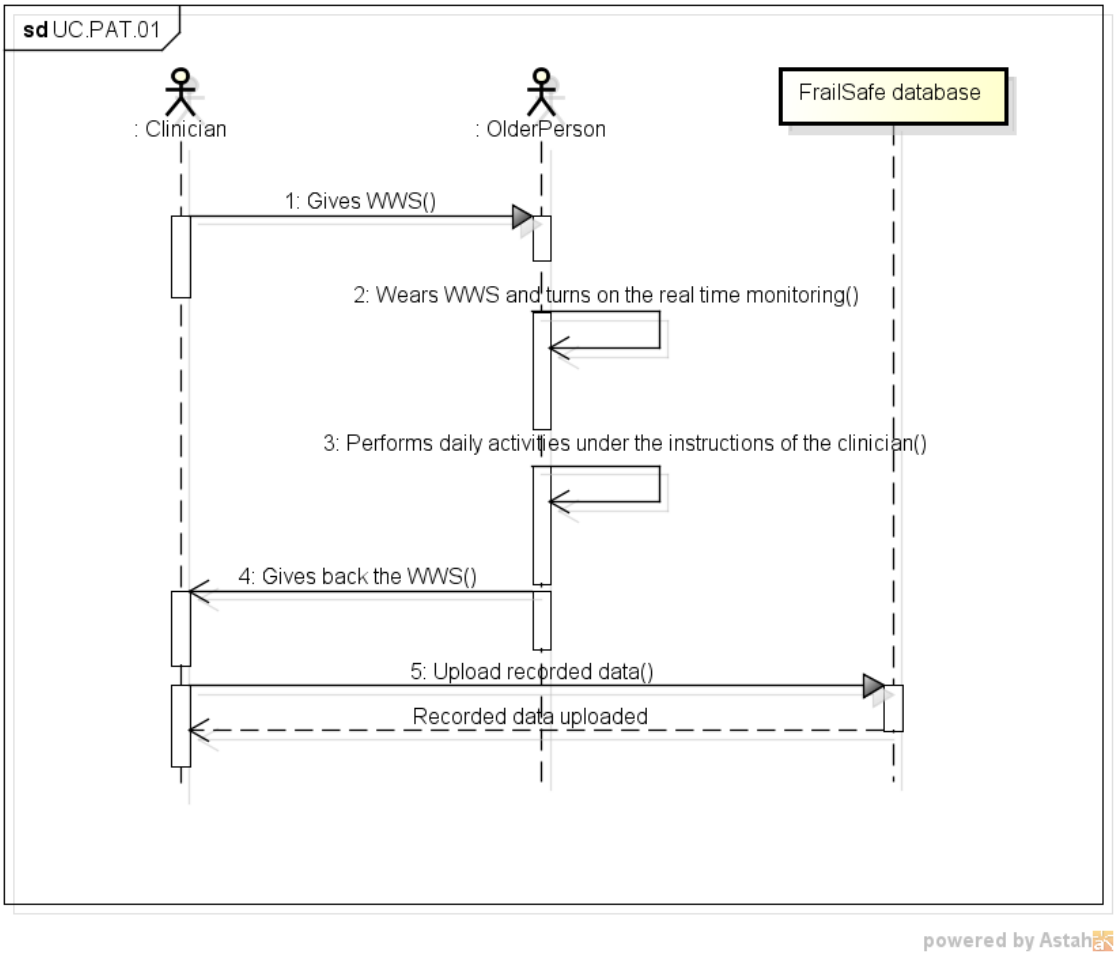
In this section, the patient-oriented use cases are presented in detail.

4.3.1 UC.PAT.01 - WWS (Wearable wellness system) - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.01 – WWS (Wearable wellness system)
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The older person performs daily activities, either indoor or outdoor, while wearing the WWS. The system records heart rate signals, respiratory signals, posture, active time, etc. The recorded data are uploaded to the FrailSafe database.
Assumptions & Pre-Conditions	• The user must correctly place the vest and turn on the electronic device • The user must charge the WWS when needed • The user must have the real-time monitoring functionality enabled. • An Internet connection is needed for the data to be uploaded to the FrailSafe database.
Goal (Successful End Condition)	• To investigate any abnormalities in the blood pressure and respiration of the users • To investigate any arrhythmia of the users • In later stages, the WWS will measure more parameters such as balance. • The recorded data must correspond to the actual values of heart rate signals, respiratory signals, and posture of the older person. • The recorded data must be uploaded to the database at most within a week from the time they were recorded.
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• Older person
Use Case Initiation	The use case is initiated when the user wears on its own the vest and turns on the electronic device which is attached to the vest at their home environment. The best scenario is to wear the vest as much time as possible, both for indoor and outdoor activities. The best readings are when the user is performing intense activity such as walking.
Main Flow	1. The user receives the WWS from the clinician. 2. The user wears the WWS and turns on the real-time monitoring functionality. 3. The user performs daily activities, under the instructions of the clinician. 4. The user gives back the WWS to the clinician.

	5. The recorded data are uploaded to the FrailSafe database.
Relationships with other Use Cases	UC.PAT.03, UC.CLI.01, UC.CLI.03
Specific Description	
Relevance to FrailSafe WPs	WP2, WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The recorded data should correspond to the actual heart rate, respiratory and posture values of the individual. The recorded data should be uploaded to the database at most within a week from the time they were recorded.
References (optional)	-
Notes (optional)	-

UML Sequence Diagram

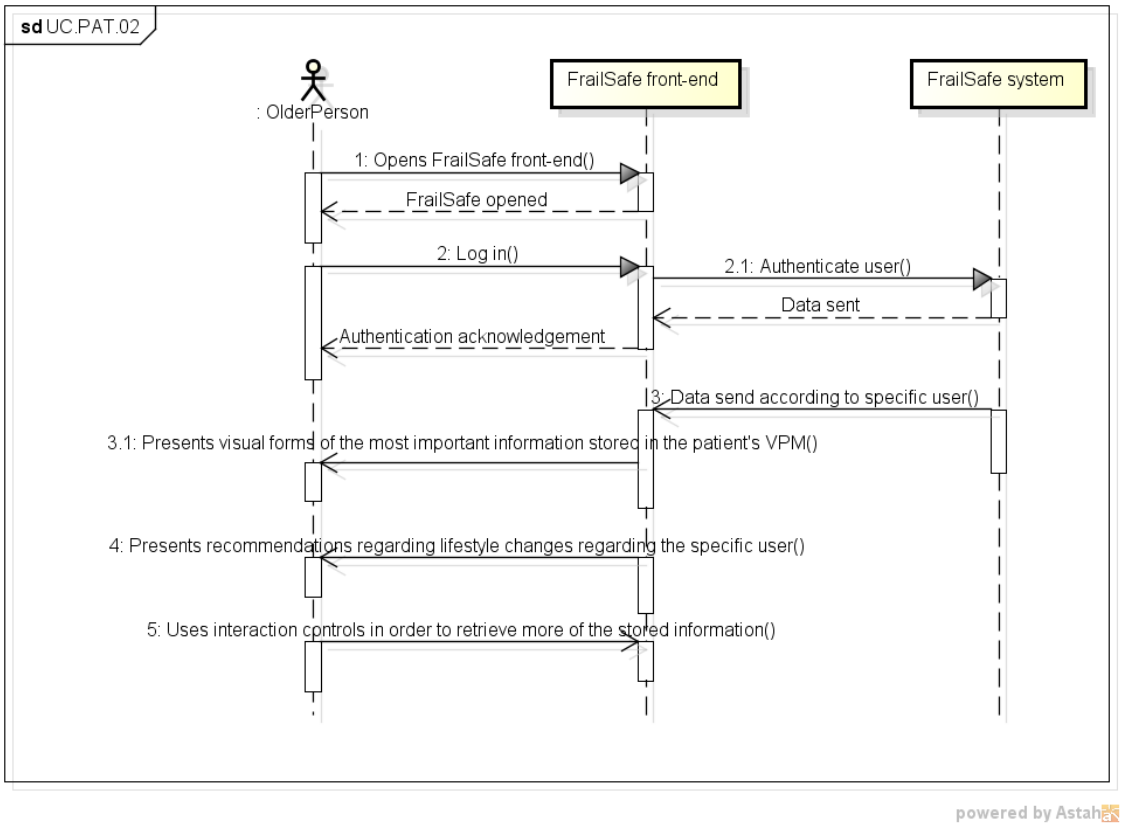


4.3.2 UC.PAT.02 – Personal data visualization - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.02 – Personal data visualization
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The user uses the mobile or web FrailSafe front-end in order to view the information stored in his/her own Virtual Patient Model, in the FrailSafe database. The virtual patient model (VPM) is a personalized profile system for the users. The personal profile facilitates the data analysis and feature extraction, supports the physician in his/her decisions, allows an adaptation to the user interfacing and a personalized feedback to the patient (suggestions about behaviour/lifestyle change/nutrition/clinical intervention etc). The information of the user is presented in simple visual forms, such as charts, graphs and histograms, in order to be instantly comprehensible. The system also presents suggestions/recommendations addressed to the user, as they have been automatically generated by the Decision Support System or manually entered by the clinician.
Assumptions & Pre-Conditions	• The user must be logged in to the FrailSafe system. • An Internet connection must be enabled.
Goal (Successful End Condition)	• To provide suggestions and interventions to the user for prevention and/or intervention purposes regarding physical, social, behavioral, nutritional, medical aspects • The visualized data must correspond to the actual data stored in the VPM for the specific user.
Post-Conditions	• The FrailSafe database remains intact.
Involved Actors	• Older person
Use Case Initiation	The use case is initiated when the user opens the FrailSafe mobile or web front-end, in order to view his/her personal collected data.
Main Flow	1. The user opens the FrailSafe mobile or web front-end. 2. The user logs in to the FrailSafe system. 3. The system presents visual forms of the most important information stored in the patient's VPM. 4. The system presents recommendations/suggestions regarding lifestyle changes, targeted to the specific older person. 5. The user uses the interaction controls of the front-end, in order to retrieve more of the stored information.
Relationships with other Use Cases	UC.FAM.01, UC.CLI.02
Specific Description	

Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The older person should be able to view only his/her personal data.
Environmental restrictions	-
Quality of service indicators	The displayed data correspond to the actual stored data in the older person's VPM. The displayed data should be instantly available to the older person, as soon as he/she requests them.
References (optional)	-
Notes (optional)	-

UML Sequence Diagram



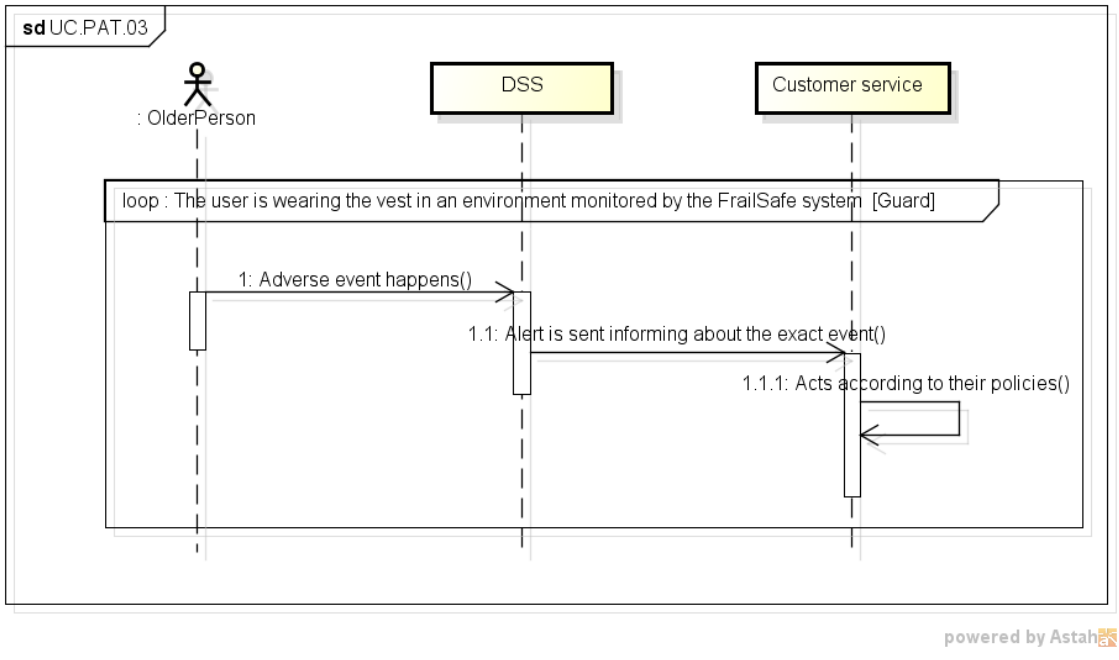
4.3.3 UC.PAT.03 - Adverse event – [FP]

Generic Description	
Use Case Name	UC.PAT.03 – Adverse event
Version	v0.1

Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	An adverse event occurs while the older person is wearing the WWS and performs daily activities, either indoor or outdoor. Adverse events that can occur are the following: • A fall • Loss of balance • Loss of orientation • Heart rate/respiration changes After an adverse event happens, a related alert is sent to the customer service call center. The Decision Support System is employed in order to decide if the event is significant enough for generating an alert. An alert may also be sent to the older person's family and clinician, depending on the configuration of their alert-receiving functionalities and on the severity of the incident. The response to such an alert is only applicable to the final FrailSafe product.
Assumptions & Pre-Conditions	• Customer service is available 24/7 • The older person must wear the WWS and be in a monitored environment, either indoors (using indoor activity monitoring devices, such as beacons) or outdoors (using outdoor activity monitoring functionalities, such as GPS tracking). • An Internet connection must be enabled on the older person's facility (for indoor) and mobile phone (for outdoor), for the alerts to be sent.
Goal (Successful End Condition)	• The customer service receives alerts from all FrailSafe systems. • The generated alerts correspond to actual events happening. • The adverse events are handled successfully, according to the customer service policies.
Post-Conditions	• The FrailSafe database is updated with data and customer services are informed in real time.
Involved Actors	• Older person • Customer service • Family • Clinician
Use Case Initiation	The use case is initiated when an adverse event happens while the user wears the vest and is in an environment monitored by the FrailSafe system.
Main Flow	1. The user is wearing the vest in an environment monitored by the FrailSafe system. 2. An adverse event happens (e.g. the older person loses balance). 3. An alert is sent to the customer service, informing it about the exact event.

	4. The customer service acts accordingly to their policies i.e. call the older person, inform a nurse, their relatives or a doctor to handle the adverse event.
Relationships with other Use Cases	UC.PAT.01, UC.PAT.04, UC.PAT.05, UC.FAM.02, UC.CLI.03
Specific Description	
Relevance to FrailSafe WPs	WP2, WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The generated alert corresponds to an actual event happening to the individual. The alert is sent to the customer service and to the families and clinicians (if applicable) at most within 10 seconds after the adverse event was detected.
References (optional)	-
Notes (optional)	-

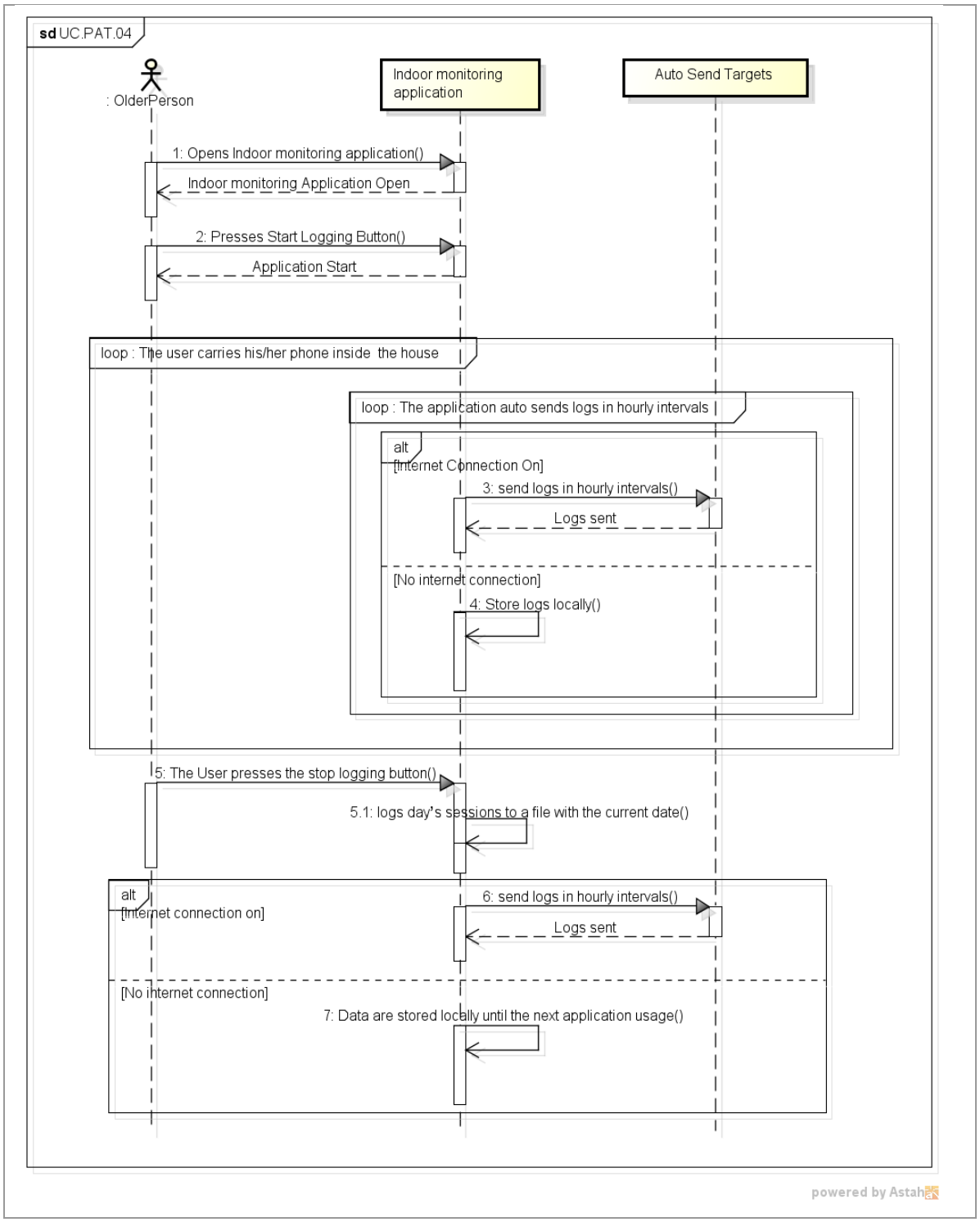
UML Sequence Diagram



4.3.4 UC.PAT.04 – Indoor activity monitoring - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.04 – Indoor activity monitoring
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The user opens the Smartphone application for indoor monitoring, which is used to track and log the indoor position of the person using it. It logs the room that the person is in at a certain time and the x and y coordinates within the facility. The recorded data are automatically uploaded to the FrailSafe database.
Assumptions & Pre-Conditions	• The FrailSafe indoor monitoring application must be installed on the user's smartphone. • The indoor monitoring devices (e.g. beacons) need to have been installed in the facility to be monitored. • An internet connection is not needed for tracking, but it is needed when the data are uploaded to the database. • The user must carry the indoor monitoring device (smartphone, smartwatch or other) with him/her either in their pocket or in their bag. Indoor activity is recorded.
Goal (Successful End Condition)	• To track and log the position of the person using it • To investigate how active the person is in the indoor environment and any patterns of movement. • Possibility to count steps (suggestions from clinicians to include pedometer as well)
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• Older person
Use Case Initiation	The use case is initiated when the user opens the indoor monitoring application and presses the start logging button.
Main Flow	1. The user opens the indoor monitoring application on the smartphone 2. The user presses the 'start logging' button 3. The user carries the phone with him/her inside the house 4. The user presses the 'stop logging' button 5. The application logs day's sessions to a file with the current date. 6. The application auto-sends logs in hourly intervals to chosen auto-send targets (which includes the Frail Safe FTP server, the custom FTP Server and e-mail address), provided that an Internet connection is on. Otherwise, the data are stored locally until the next application usage.

Relationships with other Use Cases	UC.PAT.03, UC.PAT.05, UC.CLI.06
Specific Description	
Relevance to FrailSafe WPs	WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	We receive very important information for their position, movement and indoor activity. The recorded location must have an accuracy of at least 0.5 meters distance from the actual location.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	

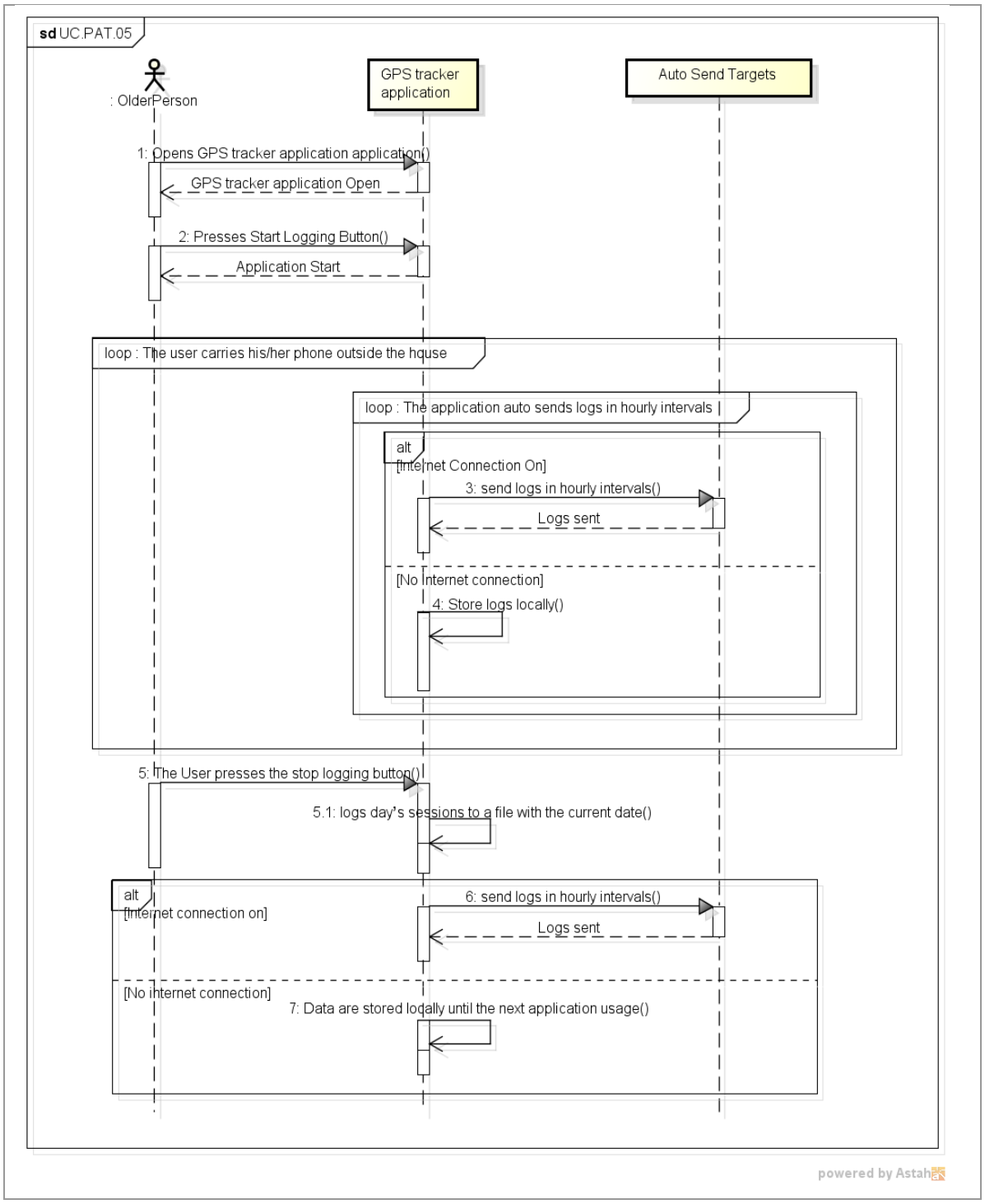


4.3.5 UC.PAT.05 – Outdoor activity monitoring - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.05 – Outdoor monitoring
Version	v0.1
Authors	CERTH, MATERIA

Last Update	December 2016
Brief Description	The user opens the Smartphone application Frailsafe GPS tracker which is used to track and log the outdoor position of the person using it. It logs latitude, longitude and other location-specific measurements. The recorded data is auto uploaded via e-mail or FTP to remote servers, including a dedicated FTP server.
Assumptions & Pre-Conditions	• The FrailSafe GPS application must be installed on the user's smartphone. • An internet connection is not needed for tracking, but it is needed when the data are uploaded to the database. • The user must carry the smartphone with him/her either in their pocket or in their bag. Outdoor activity is recorded.
Goal (Successful End Condition)	• To track and log the position of the person using it • To investigate how outgoing-social the person is • Possibility to count steps (suggestions from clinicians to include pedometer as well)
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• Older person
Use Case Initiation	The use case is initiated when the user opens the outdoor monitoring application and presses the start logging button.
Main Flow	1. The user opens the GPS tracker application on the smartphone 2. The user presses the 'start logging' button 3. The user carries the phone with him/her outside the house 4. The user presses the 'stop logging' button 5. The application logs day's sessions to a file with the current date. 6. The application auto-sends logs in hourly intervals to chosen auto-send targets (which includes the Frail Safe FTP server, the custom FTP Server and e-mail address), provided that an Internet connection is on. Otherwise, the data are stored locally until the next application usage.
Relationships with other Use Cases	UC.PAT.03, UC.PAT.04, UC.CLI.07
Specific Description	
Relevance to FrailSafe WPs	WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental	-

restrictions	
Quality of service indicators	We receive very important information for their position, movement, social life and outdoor activity. The recorded location must have an accuracy of at least 2 meters distance from the actual location.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	



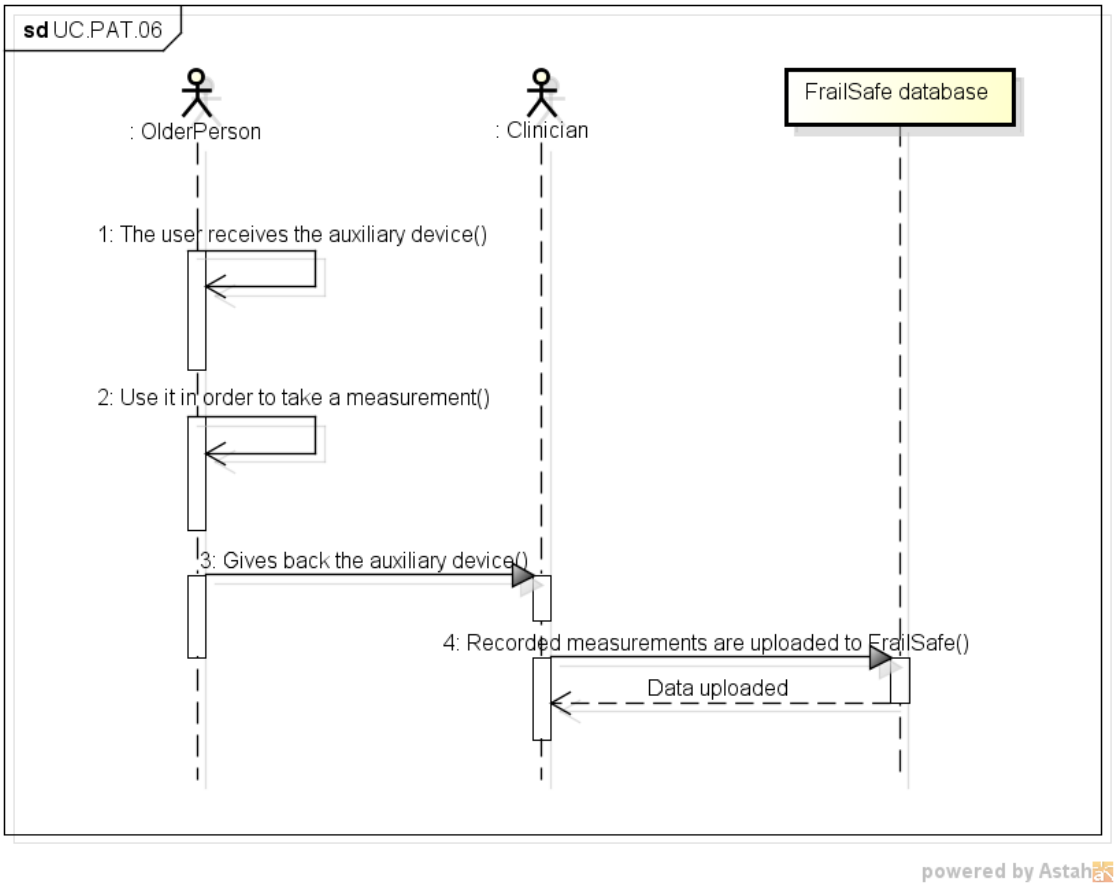
4.3.6 UC.PAT.06 – Auxiliary devices usage - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.06 – Auxiliary devices usage
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016

Brief Description	The older person uses the auxiliary devices of FrailSafe, i.e. the blood pressure monitor, the Mobil-o-graph, the dynamometer and the scales at regular intervals or after a suggestion by a clinician. The system records the measurements and uploads them to the FrailSafe database.
Assumptions & Pre-Conditions	• The older person must have access to the auxiliary devices. • The measurements taken from the dynamometer are automatically uploaded to the FrailSafe server. • The measurements from the blood pressure monitor and the scales are uploaded via the FORA telehealth system (see UC.PAT.07). • The measurements from the Mobil-o-graph are taken manually by the nurse and uploaded through the FrailSafe web clinical platform. • An Internet connection is needed for the data to be uploaded to the database.
Goal (Successful End Condition)	• The measurements from the auxiliary devices correspond to the actual values of the respective clinical parameters of the older person. • The measurements are successfully transmitted to the FrailSafe database.
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• Older person • Clinician
Use Case Initiation	The use case is initiated when the user uses any of the auxiliary devices.
Main Flow	1. The user receives the auxiliary device during the clinical evaluation and she/he is asked to use it in order to take a measurement. 2. The user gives the auxiliary device back to the clinician. 3. The recorded measurement is uploaded to the FrailSafe database.
Relationships with other Use Cases	UC.PAT.07, UC.CLI.08, UC.CLI.09
Specific Description	
Relevance to FrailSafe WPs	WP2, WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service	We receive important information from the user's blood pressure, strength, arterial stiffness and weight, which are related to the

indicators	frailty condition. The recorded data should be uploaded to the database within a week from the time they were recorded.
References (optional)	-
Notes (optional)	-

UML Sequence Diagram



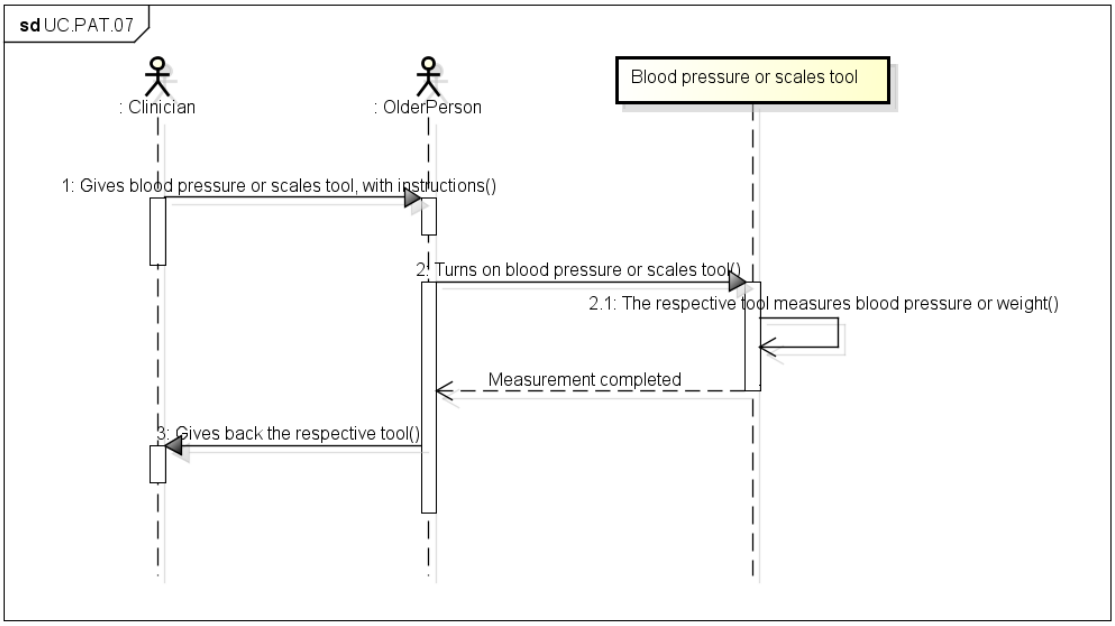
4.3.7 UC.PAT.07 - FORA telehealth system - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.07 – FORA telehealth system
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The FORA telehealth system is a website where the clinician can create a unique profile for each user and have a medical history of each user stored online. In the case of the Frail Safe project, this system is linked with the FORA blood pressure and scale tools that the users use at their home as part of their clinical frail safe

	assessment.
Assumptions & Pre-Conditions	• Each user must have their own profile and their own login details created beforehand by the clinician • Each user must be linked with a blood pressure and a scales tool on the FORA system. • The users must measure their blood pressure and weight on their own at their home environment under the instructions of the clinician.
Goal (Successful End Condition)	• To investigate any abnormalities in the blood pressure or the weight of the users • To investigate any arrhythmia of the users • Possibility for the users to be trained to use a blood pressure monitor and a scale at their home and not only for the project.
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• Older person • Clinician
Use Case Initiation	The use case is initiated when the user measures their blood pressure or their weight under specific instructions given by the clinician.
Main Flow	1. The user receives the blood pressure tool or the scales tool from the clinician, with specific instructions to follow. 2. The user turns on the blood pressure tool or the scales tool at their home 3. The respective tool measures the blood pressure or the weight of the user 4. The user gives back the blood pressure or the scales tool to the clinician.
Relationships with other Use Cases	UC.PAT.06, UC.CLI.09
Specific Description	
Relevance to FrailSafe WPs	WP2, WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The recorded data correspond to the actual blood pressure or weight values of the older person. Information is collected regarding their blood pressure and weight, issues very important in ages 70+. It might be possible to detect users with blood pressure or weight issues and give them

	recommendations.
References (optional)	-
Notes (optional)	-

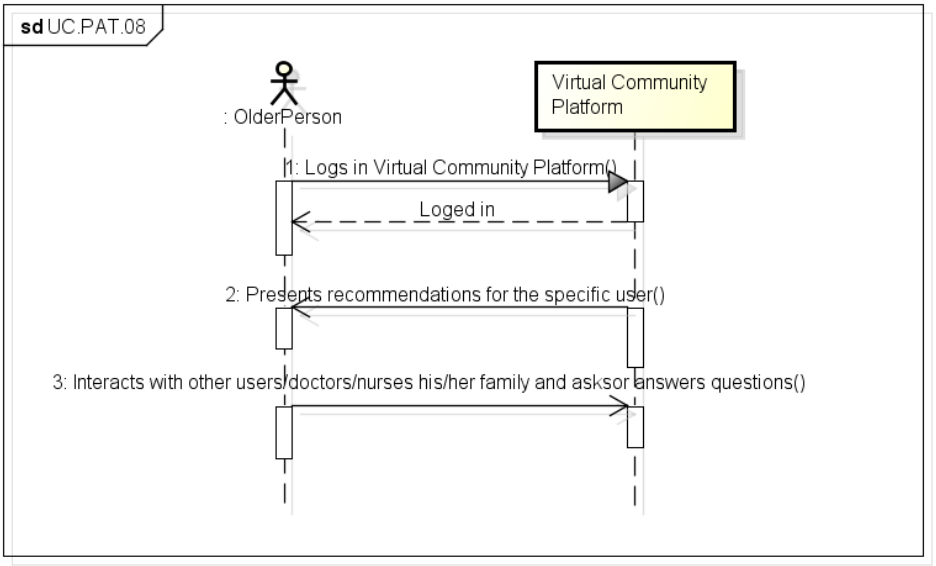
UML Sequence Diagram



4.3.8 UC.PAT.08 - Virtual community platform - [FP]

Generic Description	
Use Case Name	UC.PAT.08 – Virtual community platform
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The older person uses the virtual community platform in order to discuss with peers and clinicians. The virtual community platform supports interactions among peers having similar health issues, to exchange disease and health related information, promotes positive health-related activities (fitness, daily habits, and environmental safety), education and training whenever required. The older person may also ask questions about diagnoses, etiology and treatment, which are answered not only by medical doctors but also by other older people and family members.
Assumptions & Pre-Conditions	• An Internet connection must be enabled. • The older person must have an account for the virtual community platform.
Goal (Successful	• The user uses the virtual community platform and gets information and suggestions regarding his/her health and

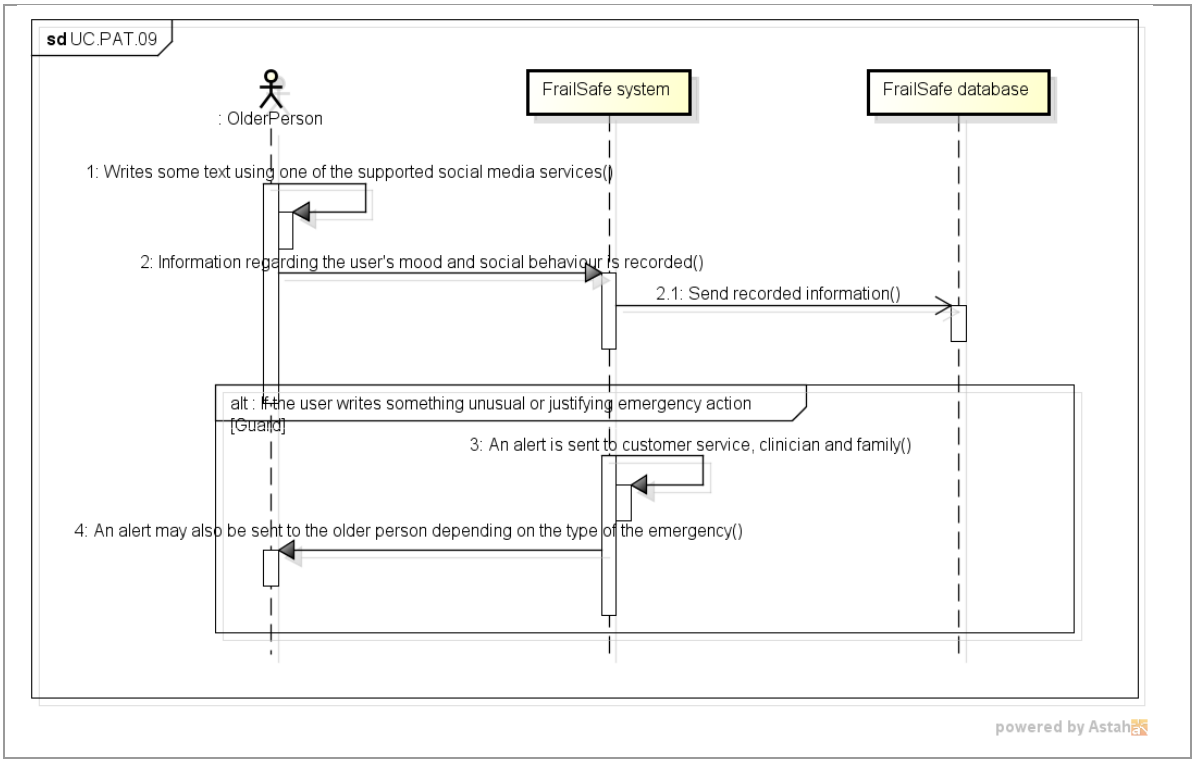
End Condition)	interacts with others.
Post-Conditions	• The Virtual Community Platform is ready to accept new comments and questions.
Involved Actors	• Older people • Clinicians • Families
Use Case Initiation	The use case is initiated when the user uses the virtual community platform.
Main Flow	1. The user logs in to the virtual community platform. 2. The user views recommendations prepared for him/her. 3. The user interacts with other users, or/and doctors/nurses and/or his/her family and asks or/and answers questions.
Relationships with other Use Cases	UC.FAM.03, UC.CLI.05
Specific Description	
Relevance to FrailSafe WPs	WP6
Privacy & Regulation restrictions	The information exchanged among the older persons, the clinicians and the families should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The information provided or the questions asked by the older person should be instantly available to the persons to whom they are addressed.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	



4.3.9 UC.PAT.09 - Social media usage - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.09 – Social media usage
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The older person regularly uses social media (e.g. Facebook, Twitter, e-mail, etc.). The system analyses the written discussions and records mood-, social- and behaviour-related information to the FrailSafe database. The system also records metadata, such as the number of text messages written, the times written, etc. In case the written text includes information that signals an emergency situation, an alert is sent to the customer service, as well as to the family and clinicians, depending on their alert-receiving configuration. Although the text analysis is part of the development-phase use cases, the alert-handling part is only applicable to the final FrailSafe product.
Assumptions & Pre-Conditions	• An Internet connection must be enabled. • The user has an account and uses at least one of the social media tools.
Goal (Successful End Condition)	• The user uses the social media • The database receives information for the usage of social media from the user • An alert is sent to a responsible person, in case an unusual situation is detected.
Post-Conditions	• The FrailSafe database is updated with data

Involved Actors	• Older person • Customer service • Clinician • Family
Use Case Initiation	The use case is initiated when the user uses the various social media. The alert-related functionality is initiated when the user writes something unusual.
Main Flow	1. The user writes some text using one of the supported social media services. 2. Information regarding the user's mood and social behaviour is recorded by the system. 3. The recorded information is transmitted to the FrailSafe database. If the user writes something unusual or justifying emergency actions, an alert is sent to the customer service, clinician and family. An alert or recommendation may also be sent to the older person himself/herself, depending on the type of the emergency.
Relationships with other Use Cases	UC.PAT.03
Specific Description	
Relevance to FrailSafe WPs	WP4,
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	



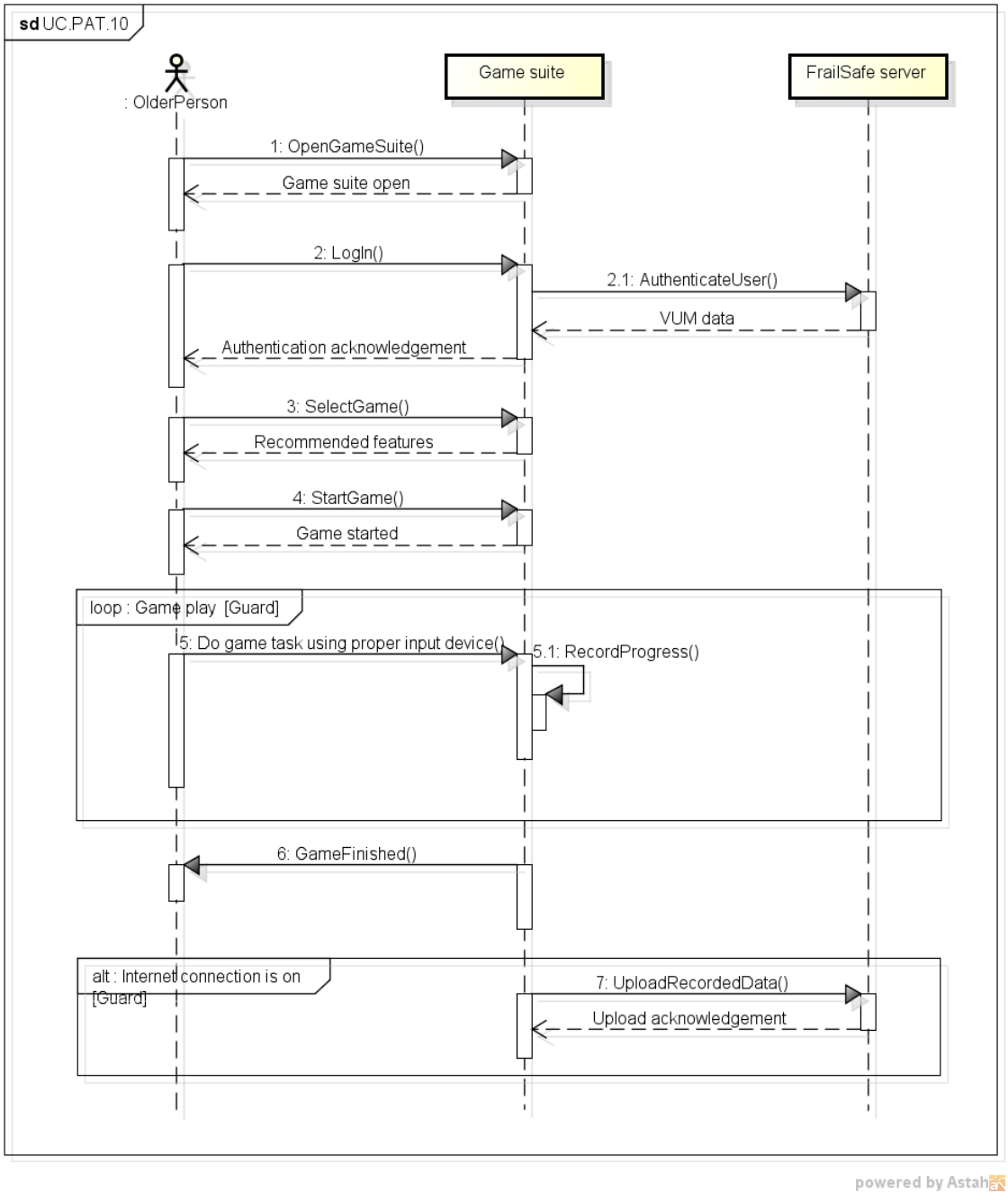
4.3.10 UC.PAT.10 - Physical game usage - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.10 – Physical game usage
Version	v0.1
Authors	CERTH, SIGLA
Last Update	December 2016
Brief Description	The user opens the FrailSafe game suite, either on the tablet or the PC, and selects a physical game to play, i.e. a game involving physical activity. The physical games require the interaction of the user with one (or more) of the following devices: • Dynamometer • IMUs • AR glasses The system recommends a game with tasks and difficulty level appropriate for the frailty level and the medical condition of the specific user. The user plays the recommended game by trying to accomplish the tasks requested by it. The performance of the user is recorded by the FrailSafe system. The recorded data are stored locally and are transmitted to the online FrailSafe server as soon as an Internet connection is available.
Assumptions & Pre-Conditions	• The FrailSafe game suite should be installed on the user's tablet or PC. • The user should be logged in to the game suite with his/her FrailSafe account.

	• The online FrailSafe cloud server should be running.
Goal (Successful End Condition)	• The user plays an interesting game that challenges his/her physical capabilities. • The user's performance to the game is stored to the FrailSafe online server.
Post-Conditions	• The FrailSafe database is updated with new data. • The FrailSafe game suite is ready to initiate a new game session.
Involved Actors	• Older person
Use Case Initiation	The use case is initiated when the user desires to play a physical activity-related game, out of his/her initiative or following the clinician's recommendation.
Main Flow	1. The user opens the FrailSafe game suite from the tablet. 2. The user logs in with his/her FrailSafe account (could be already logged in). 3. The user selects a physical activity-related game. 4. The system recommends game features (tasks, levels, difficulty, etc.) for the specific user. 5. The user starts the game with the recommended settings. 6. The user plays the game, using the needed interaction device (dynamometer, IMUs, AR glasses). 7. The user performance (successful tasks, time to fulfill the tasks, etc.) are recorded locally. 8. The user finishes the game. 9. The game checks for an Internet connection. 10. If an internet connection is on, the recorded data, and any previously recorded and unsent data, are transmitted to the FrailSafe online server. Otherwise, they stay stored locally, until the next playing of a game.
Relationships with other Use Cases	UC.CLI.10
Specific Description	
Relevance to FrailSafe WPs	WP5, WP4, WP6
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service	The recommended game features (difficulty level, tasks, etc.) are

indicators	relevant to the frailty status of the user. The recorded data become available in the FrailSafe server at most after a week.
References (optional)	-
Notes (optional)	-

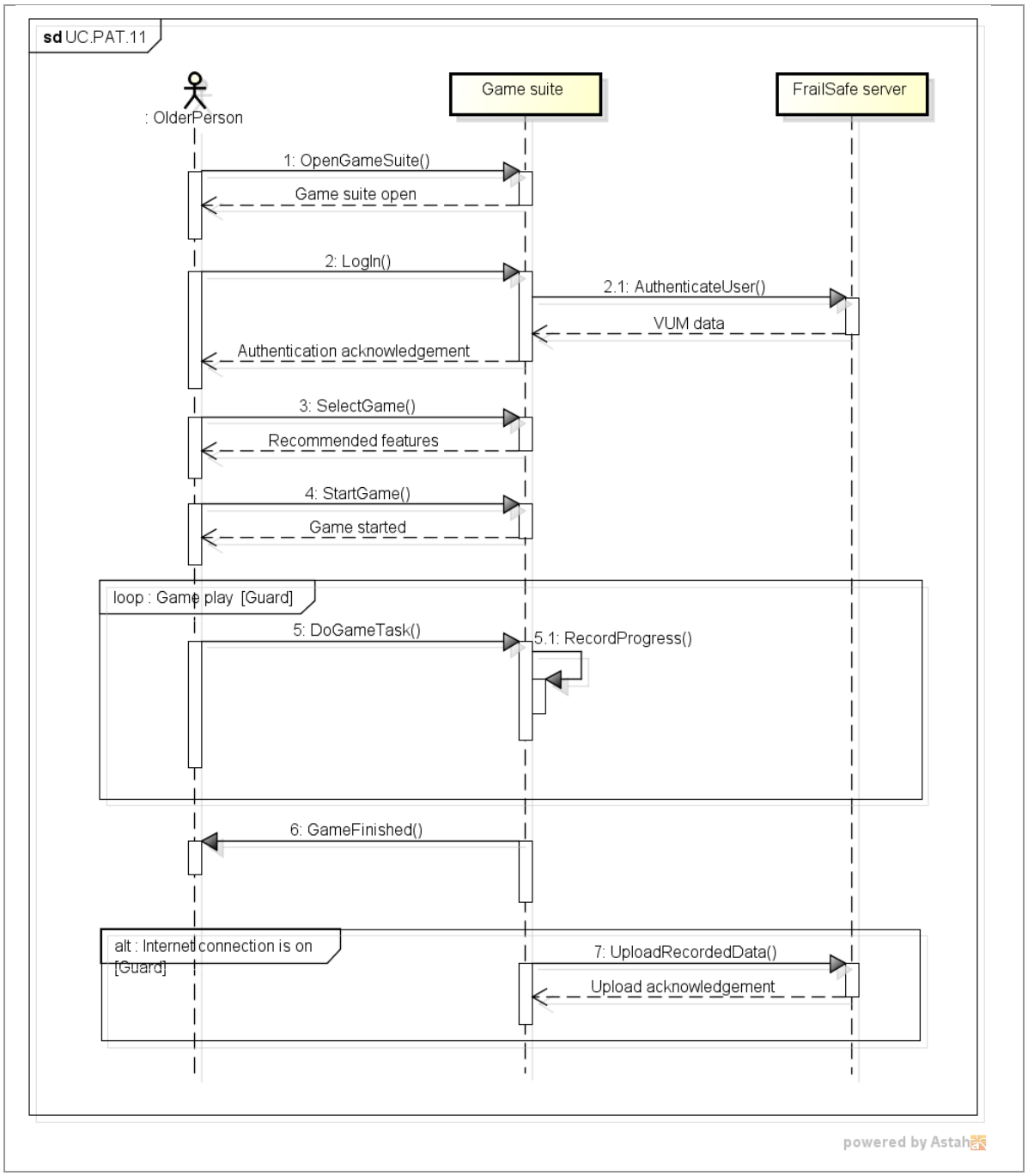
UML Sequence Diagram



4.3.11 UC.PAT.11 - Cognitive game usage - [DP] [FP]

Generic Description	
Use Case Name	UC.PAT.11 – Cognitive game usage
Version	v0.1
Authors	CERTH, SIGLA
Last Update	December 2016
Brief Description	The user opens the FrailSafe game suite on the tablet and selects a cognitive game to play. The system recommends a game with tasks and difficulty level appropriate for the frailty level and the cognitive condition of the specific user. The user plays the recommended game by trying to accomplish the cognitive tasks requested by it. The performance of the user is recorded by the FrailSafe system. The recorded data are stored locally on the tablet and are transmitted to the online FrailSafe server as soon as an Internet connection is available.
Assumptions & Pre-Conditions	• The FrailSafe game suite should be installed on the user's tablet. • The user should be logged in to the game suite with his/herFrailSafe account. • The online FrailSafe cloud server should be running.
Goal (Successful End Condition)	• The user plays an interesting game that challenges his/her cognitive capabilities. • The user's performance to the game is stored to the FrailSafeonline server.
Post-Conditions	• The FrailSafe database is updated with new data. • The FrailSafe game suite is ready to initiate a new game session.
Involved Actors	• Older person
Use Case Initiation	The use case is initiated when the user desires to play a cognitive game, out of his/her initative or following the clinician's recommendation.
Main Flow	11. The user opens the FrailSafe game suite from the tablet. 12. The user logs in with his/her FrailSafe account (could be already logged in). 13. The user selects a cognitive game. 14. The system recommends game features (tasks, levels, difficulty, etc.) for the specific user. 15. The user starts the game with the recommended settings. 16. The user plays the game. 17. The user performance (successful tasks, time to fulfill the tasks, etc.) are recorded locally on the tablet.

	18. The user finishes the game. 19. The game checks for an Internet connection. 20. If an internet connection is on, the recorded data, and any previously recorded and unsent data, are transmitted to the FrailSafe online server. Otherwise, they stay stored locally, until the next playing of a game.
Relationships with other Use Cases	UC.CLI.10
Specific Description	
Relevance to FrailSafe WPs	WP5, WP4, WP6
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The recommended game features (difficulty level, tasks, etc.) are relevant to the frailty status of the user. The recorded data become available in the FrailSafe server at most after a week.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	


sd UC.PAT.11
: OlderPerson
Game suite
FrailSafe server
1: OpenGameSuite()
Game suite open
2: LogIn()
2.1: AuthenticateUser()
VUM data
Authentication acknowledgement
3: SelectGame()
Recommended features
4: StartGame()
Game started
loop : Game play [Guard]
5: DoGameTask()
5.1: RecordProgress()
6: GameFinished()
alt : Internet connection is on [Guard]
7: UploadRecordedData()
Upload acknowledgement
powered by Astah

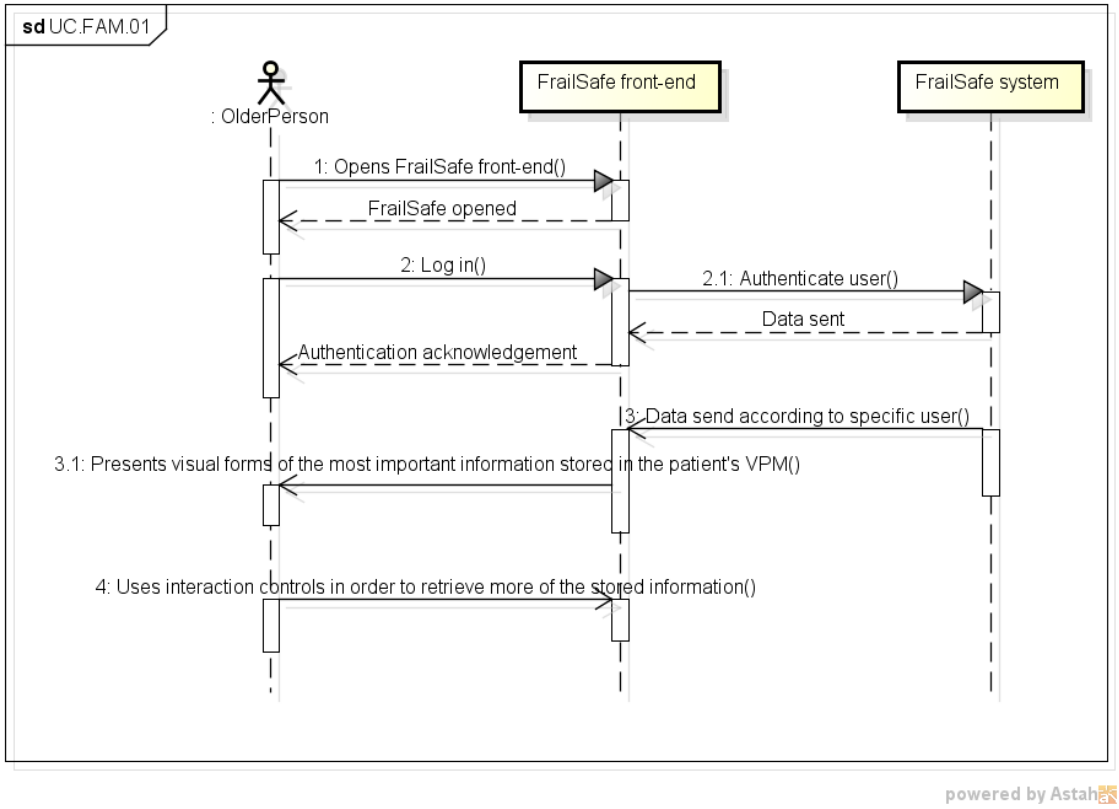
4.4 Family-oriented use cases

4.4.1 UC.FAM.01 – Older person data visualization - [DP] [FP]

Generic Description	
Use Case Name	UC.FAM.01 – Older person data visualization
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The family member uses the mobile or web FrailSafe front-end in order to view the information stored in the Virtual Patient Model of their related older person. The older person's information is presented in simple visual forms, such as charts, graphs and histograms, in order to be instantly comprehensible.
Assumptions & Pre-Conditions	• The user must be logged in to the FrailSafe system. • An Internet connection must be enabled.
Goal (Successful End Condition)	• The visualized data must correspond to the actual data stored in the VPM for the specific older person.
Post-Conditions	• The FrailSafe database remains intact.
Involved Actors	• Family
Use Case Initiation	The use case is initiated when the family members open the FrailSafe mobile or web front-end, in order to view the data collected for their related older person.
Main Flow	1. The user opens the FrailSafe mobile or web front-end. 2. The user logs in to the FrailSafe system. 3. The system presents visual forms of the most important information stored in the patient's VPM. 4. The user uses the interaction controls of the front-end, in order to retrieve more of the stored information.
Relationships with other Use Cases	UC.PAT.02, UC.CLI.02
Specific Description	
Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The family members should be able to view only the data collected for their related older person.
Environmental restrictions	-
Quality of service indicators	The displayed data correspond to the actual stored data in the older person's VPM. The displayed data should be instantly available to the family member, as soon as he/she requests them.

References (optional)	-
Notes (optional)	-

UML Sequence Diagram



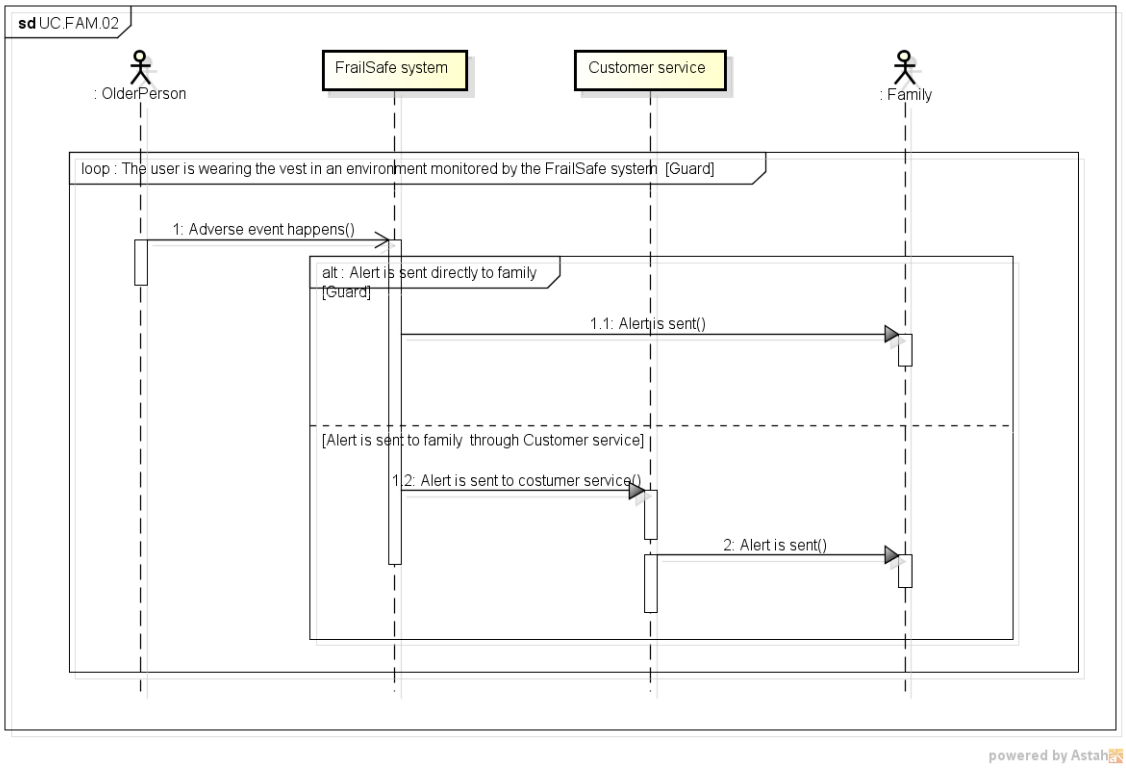
4.4.2 UC.FAM.02 – Adverse event – [FP]

Generic Description	
Use Case Name	UC.FAM.02 – Adverse event
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	An adverse event occurs while the older person is wearing the WWS and performs daily activities, either indoor or outdoor. Adverse events that can occur are the following: • A fall • Loss of balance • Loss of orientation • Heart rate/respiration changes After an adverse event happens, a related alert is sent to the family member, either directly or through the customer service, depending on his/her configuration of the alert-receiving functionalities and on the severity of the incident. The response to

	such an alert is only applicable to the final FrailSafe product.
Assumptions & Pre-Conditions	• Customer service is available 24/7 • The older person must wear the WWS and be in a monitored environment, either indoors (using indoor activity monitoring devices, such as beacons) or outdoors (using outdoor activity monitoring functionalities, such as GPS tracking). • An Internet connection must be enabled on the older person's facility (for indoor) and mobile phone (for outdoor), for the alerts to be sent. • The family member must have the FrailSafe application open. • The family member must be logged in to the FrailSafe system.
Goal (Successful End Condition)	• The family member receives alerts for the incidents of the configured severity. • The generated alerts correspond to actual events happening.
Post-Conditions	• The FrailSafe database is updated with data and customer services are informed in real time.
Involved Actors	• Family • Older person • Customer service
Use Case Initiation	The use case is initiated when an adverse event happens while the older person wears the vest and is in an environment monitored by the FrailSafe system.
Main Flow	1. The older person is wearing the vest in an environment monitored by the FrailSafe system. 2. An adverse event happens (e.g. the older person loses balance). 3. An alert is sent to the family member, informing it about the exact event. The alert originates either from the system directly or from the customer service.
Relationships with other Use Cases	UC.PAT.01, UC.PAT.03, UC.CLI.03
Specific Description	
Relevance to FrailSafe WPs	WP2, WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The generated alert corresponds to an actual event happening to the individual. The direct alert is sent to the families at most within 10 seconds

	after the adverse event was detected. The alert through the customer service is sent to the families at most within 2 minutes after the adverse event was detected.
References (optional)	-
Notes (optional)	-

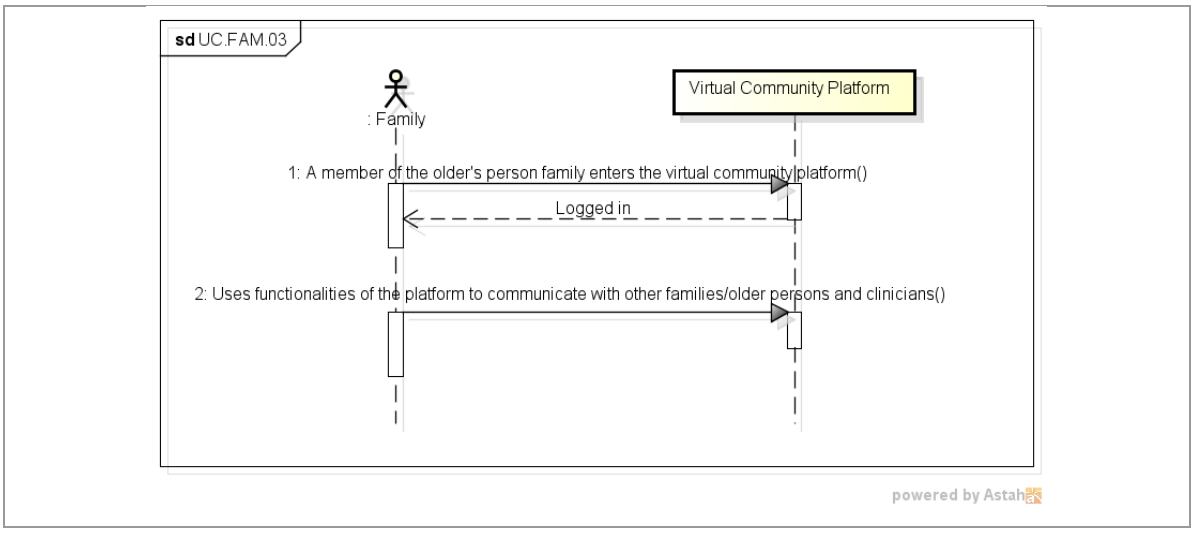
UML Sequence Diagram



4.4.3 UC.FAM.03 – Virtual community platform - [FP]

Generic Description	
Use Case Name	UC.FAM.03 – Virtual community platform
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The family and relatives of the older person use the Virtual Community Platform to communicate with the community of older persons, relatives and clinicians, in order to exchange opinions or answer to questions posed by older persons.
Assumptions & Pre-Conditions	• An Internet connection must be enabled. • Families use the Virtual community platform • Users use the Virtual community platform

Goal (Successful End Condition)	• The families use the Virtual community platform to check the progress of the users answers their possible questions.
Post-Conditions	• The Virtual Community Platform is ready to accept new comments and questions.
Involved Actors	• Family • Older person • Clinician
Use Case Initiation	The use case is initiated when families use the virtual community platform.
Main Flow	1. A member of the older person's family enters the virtual community platform. 2. The family member uses the functionalities of the platform to communicate with other families, older persons and clinicians.
Relationships with other Use Cases	UC.PAT.08, UC.CLI.05
Specific Description	
Relevance to FrailSafe WPs	WP6
Privacy & Regulation restrictions	The information exchanged among the families, the older persons and the clinicians should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The information provided or the questions asked by the family members should be instantly available to the persons to whom they are addressed.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	


sd UC.FAM.03
: Family
Virtual Community Platform
1: A member of the older's person family enters the virtual community platform()
Logged in
2: Uses functionalities of the platform to communicate with other families/older persons and clinicians()
powered by Astah

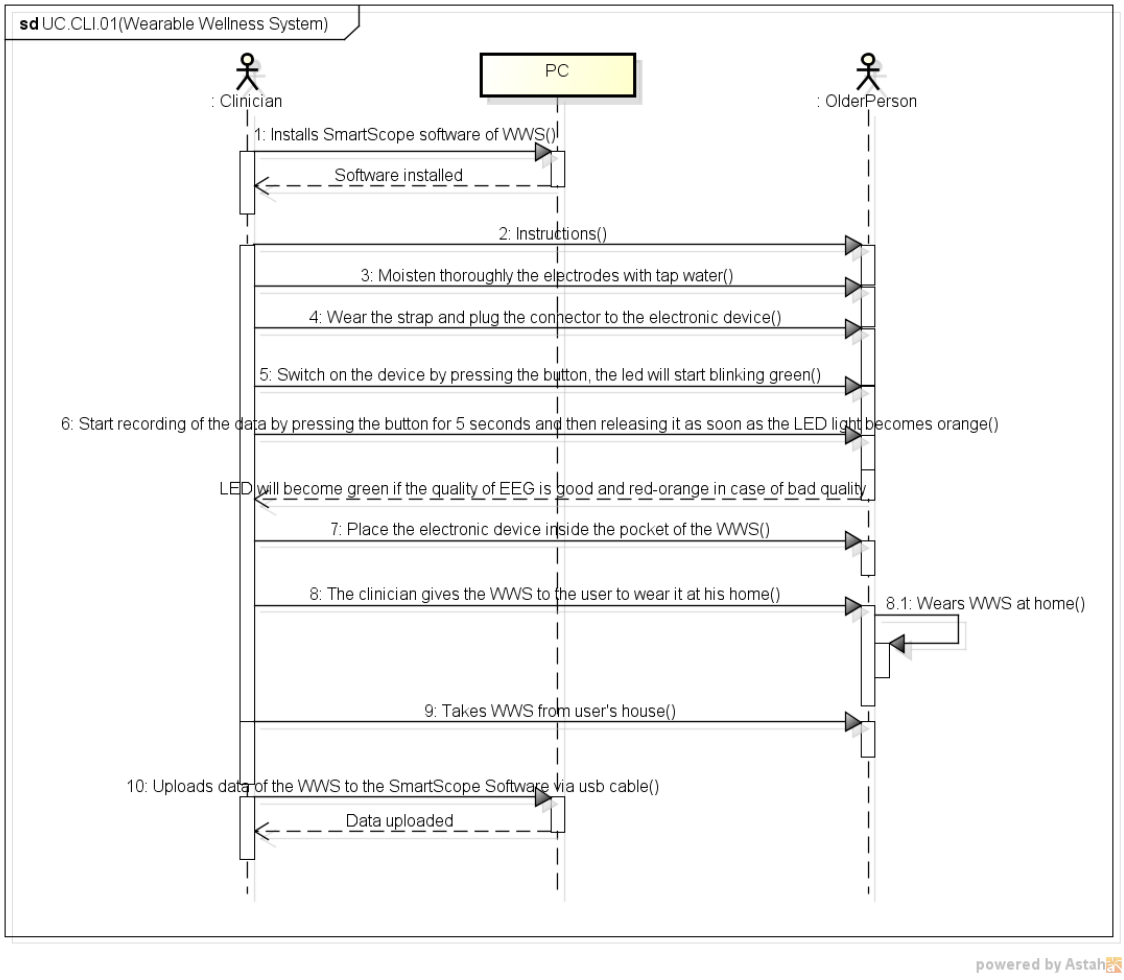
4.5 Healthcare professional-oriented use cases

4.5.1 UC.CLI.01 - WWS (Wearable wellness system) preparation - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.01 – WWS (Wearable wellness system) preparation
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The clinician prepares the WWS for the older person to wear. After the measurement sessions, the clinician collects the measurements and uploads them to the database.
Assumptions & Pre-Conditions	• The WWS must be charged.
Goal (Successful End Condition)	• To investigate any abnormalities in the blood pressure and respiration of the users • To investigate any arrhythmia of the users • In later stages, the WWS will measure more parameters such as balance.
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• Clinician
Use Case Initiation	The use case is initiated when the clinician sets up the WWS and gives it to the user at his/her house with specific instructions
Main Flow	1. The clinician installs on the PC the SmartScope software of the WWS 2. The clinician gives the following instructions to the user: 1. Moisten thoroughly the electrodes with tap water 2. Wear the strap and plug the connector to the electronic device 3. Switch on the device by pressing the button, the led will start blinking green 4. Start recording of the data by pressing the button for 5 seconds and then releasing it as soon as the LED light becomes orange. If ECG quality is good, the LED light will be green, if the quality is bad the light will be red-orange. 5. Place the electronic device inside the pocket of the WWS 3. The clinician gives the WWS to the user to wear it at his home. 4. The clinician takes the WWS from the user's house. 5. The clinician uploads the data of the WWS to the SmartScope software on the computer via usb cable.
Relationships with other Use Cases	UC.PAT.01
Specific Description	
Relevance to FrailSafe WPs	WP2, WP3, WP4

Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	Able to investigate respiration and blood pressure of the users and being able to give recommendation when needed
References (optional)	-
Notes (optional)	-

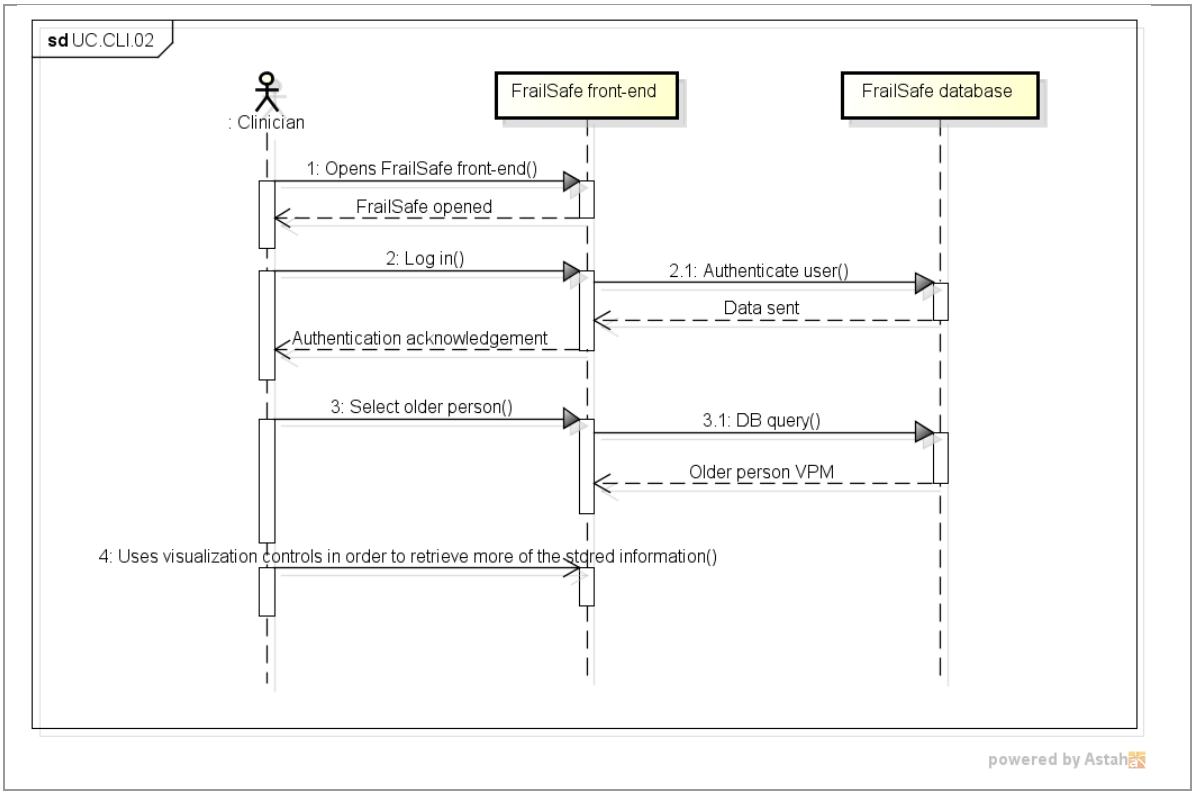
UML Sequence Diagram



4.5.2 UC.CLI.02 – Older person data visualization - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.02 – Older person data visualization
Version	v0.1
Authors	CERTH, MATERIA

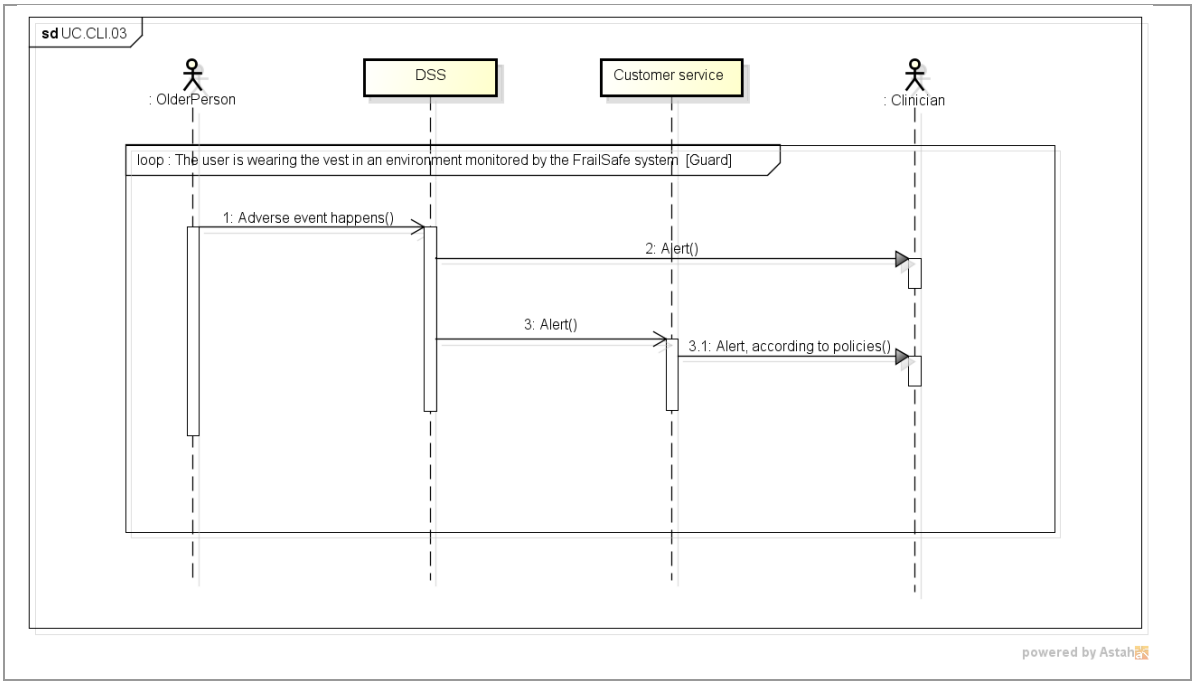
Last Update	December 2016
Brief Description	The clinician uses the mobile or web FrailSafe front-end in order to view the information stored in the Virtual Patient Model of an older person. The older person's information is presented in simple visual forms, such as charts, graphs and histograms, as well as in more elaborate visual analytics methods, in order to allow the clinician to explore the available data.
Assumptions & Pre-Conditions	• The clinician must be logged in to the FrailSafe system. • An Internet connection must be enabled.
Goal (Successful End Condition)	• The visualized data must correspond to the actual data stored in the VPM for the specific older person.
Post-Conditions	• The FrailSafe database remains intact.
Involved Actors	• Clinician
Use Case Initiation	The use case is initiated when the clinician opens the FrailSafe mobile or web front-end, in order to view the data collected for a specific older person.
Main Flow	1. The clinician opens the FrailSafe mobile or web front-end. 2. The clinician logs in to the FrailSafe system. 3. The system presents visualizations of the data stored in the older person's VPM. 4. The user uses the interaction controls of the front-end, in order navigate in the visualizations and retrieve more detailed information.
Relationships with other Use Cases	UC.PAT.02, UC.FAM.01, UC.RES.03
Specific Description	
Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The clinician should be able to view only the data collected for the older persons under their supervision.
Environmental restrictions	-
Quality of service indicators	The displayed data correspond to the actual stored data in the older person's VPM. The displayed data should be instantly available to the clinician, as soon as he/she requests them.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	



4.5.3 UC.CLI.03 – Adverse event – [FP]

Generic Description	
Use Case Name	UC.CLI.03 – Adverse event
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	An adverse event occurs while the older person is wearing the WWS and performs daily activities, either indoor or outdoor. Adverse events that can occur are the following: • A fall • Loss of balance • Loss of orientation • Heart rate/respiration changes After an adverse event happens, a related alert is sent to the clinician, either directly or through the customer service, depending on his/her configuration of the alert-receiving functionalities and on the severity of the incident. The response to such an alert is only applicable to the final FrailSafe product.
Assumptions & Pre-Conditions	• Customer service is available 24/7 • The older person must wear the WWS and be in a monitored environment, either indoors (using indoor activity monitoring devices, such as beacons) or outdoors (using outdoor activity monitoring functionalities, such as GPS tracking).

	• An Internet connection must be enabled on the older person's facility (for indoor) and mobile phone (for outdoor), for the alerts to be sent. • The clinician must have the FrailSafe application open. • The clinician must be logged in to the FrailSafe system.
Goal (Successful End Condition)	• The clinician receives alerts for the incidents of the configured severity. • The generated alerts correspond to actual events happening.
Post-Conditions	• The FrailSafe database is updated with data and customer services are informed in real time.
Involved Actors	• Clinician • Older person • Customer service
Use Case Initiation	The use case is initiated when an adverse event happens while the older person wears the vest and is in an environment monitored by the FrailSafe system.
Main Flow	1. The older person is wearing the vest in an environment monitored by the FrailSafe system. 2. An adverse event happens (e.g. the older person loses balance). 3. An alert is sent to the clinician, informing it about the exact event. The alert originates either from the system directly or from the customer service.
Relationships with other Use Cases	UC.PAT.03, UC.FAM.03
Specific Description	
Relevance to FrailSafe WPs	WP2, WP3, WP4
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The generated alert corresponds to an actual event happening to the individual. The direct alert is sent to the clinician at most within 10 seconds after the adverse event was detected. The alert through the customer service is sent to the clinician at most within 2 minutes after the adverse event was detected.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	

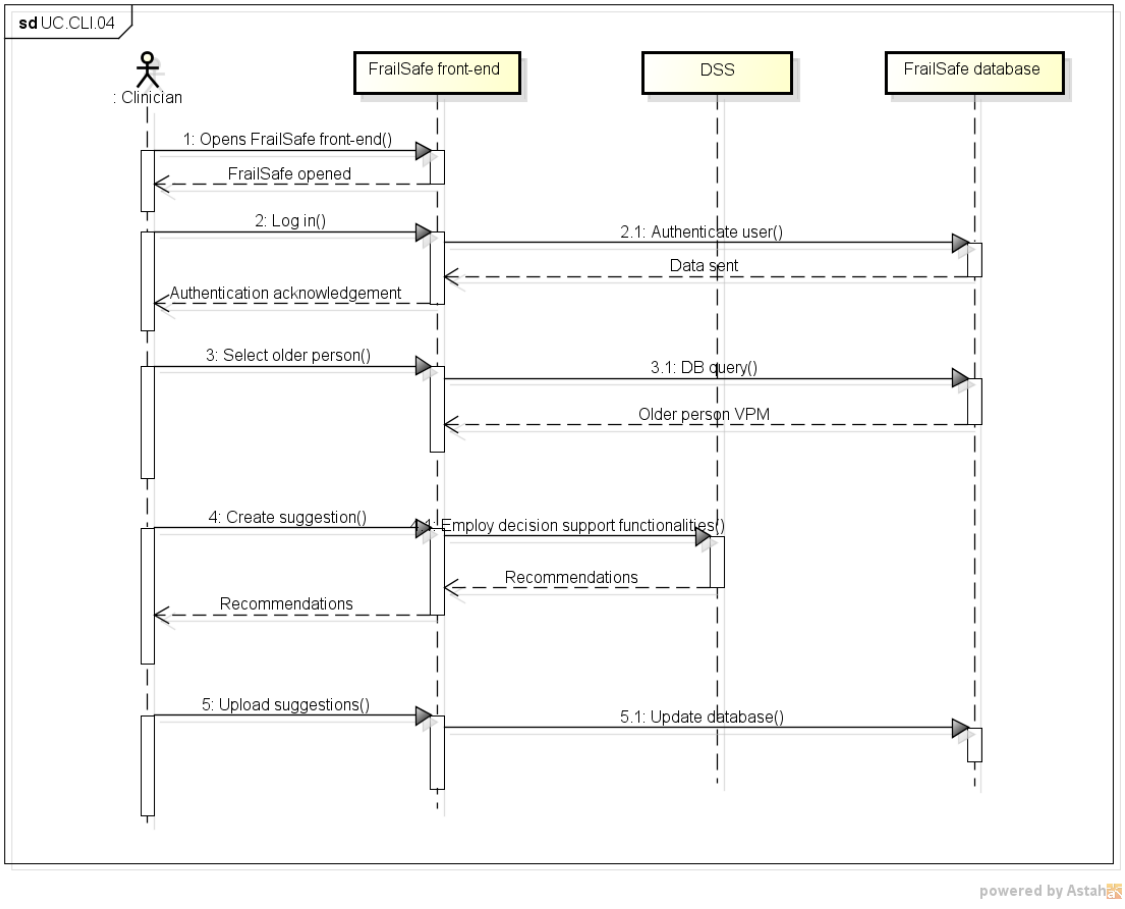


4.5.4 UC.CLI.04 – Clinician suggestions - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.04 – Clinician suggestions
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	A clinician uses the FrailSafe web or mobile front-end to provide suggestions to an older person regarding lifestyle changes. The clinician uses the FrailSafe Decision Support System (DSS) to assist him/her in recommending specific actions from the older person.
Assumptions & Pre-Conditions	• An Internet connection must be enabled. • The clinician must be logged in to the FrailSafe system.
Goal (Successful End Condition)	• The clinician's suggestion is logged in the FrailSafe database. • The older person can see the clinician's suggestion when he/she uses the mobile or web front-end.
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• Clinician
Use Case Initiation	The use case is initiated when the clinician wishes to submit a suggestion/recommendation to the older person.
Main Flow	1. The clinician opens the FrailSafe mobile or web front-end. 2. The clinician logs in. 3. The clinician uses the front-end features and the DSS in order to create a new suggestion for an older person.

	4. The clinician submits the suggestion to the system. 5. The suggestion is stored to the FrailSafe database, in order to appear to the older person's front-end when the latter logs in.
Relationships with other Use Cases	UC.CLI.02, UC.RES.03
Specific Description	
Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The suggestion created by the clinician is available to appear in the older person's front-end within at most 1 hour from the time it was created by the clinician.
References (optional)	-
Notes (optional)	-

UML Sequence Diagram

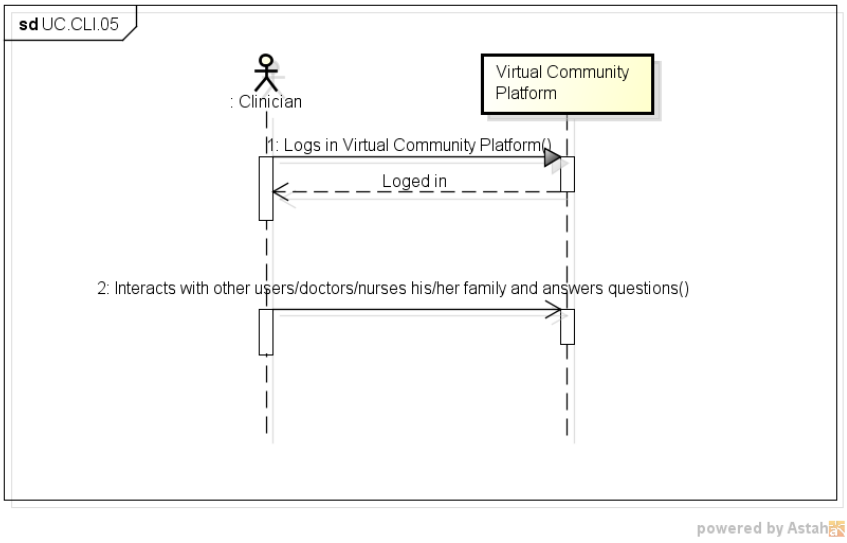


4.5.5 UC.CLI.05 – Virtual community platform - [FP]

Generic Description	
Use Case Name	UC.CLI.05 – Virtual community platform
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The clinician uses the Virtual Community Platform to communicate with the community of older persons, relatives and clinicians, in order to exchange opinions or answer to questions posed by older persons.
Assumptions & Pre-Conditions	• An Internet connection must be enabled. • Families use the Virtual community platform • Older persons use the Virtual community platform
Goal (Successful End Condition)	• The clinician uses the Virtual community platform to check the progress of the users and answer their possible questions.
Post-Conditions	• The Virtual Community Platform is ready to accept new comments and answers.
Involved Actors	• Clinician • Older person • Family
Use Case Initiation	The use case is initiated when a clinician uses the virtual community platform.
Main Flow	1. The clinician enters the virtual community platform. 2. The clinician uses the functionalities of the platform to communicate with older persons, families and other clinicians.
Relationships with other Use Cases	UC.PAT.08, UC.FAM.03
Specific Description	
Relevance to FrailSafe WPs	WP6
Privacy & Regulation restrictions	The information exchanged among the clinicians, the older persons and the families should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The information provided or the questions answered by the clinician should be instantly available to the persons to whom they are addressed.

References (optional)	-
Notes (optional)	-

UML Sequence Diagram

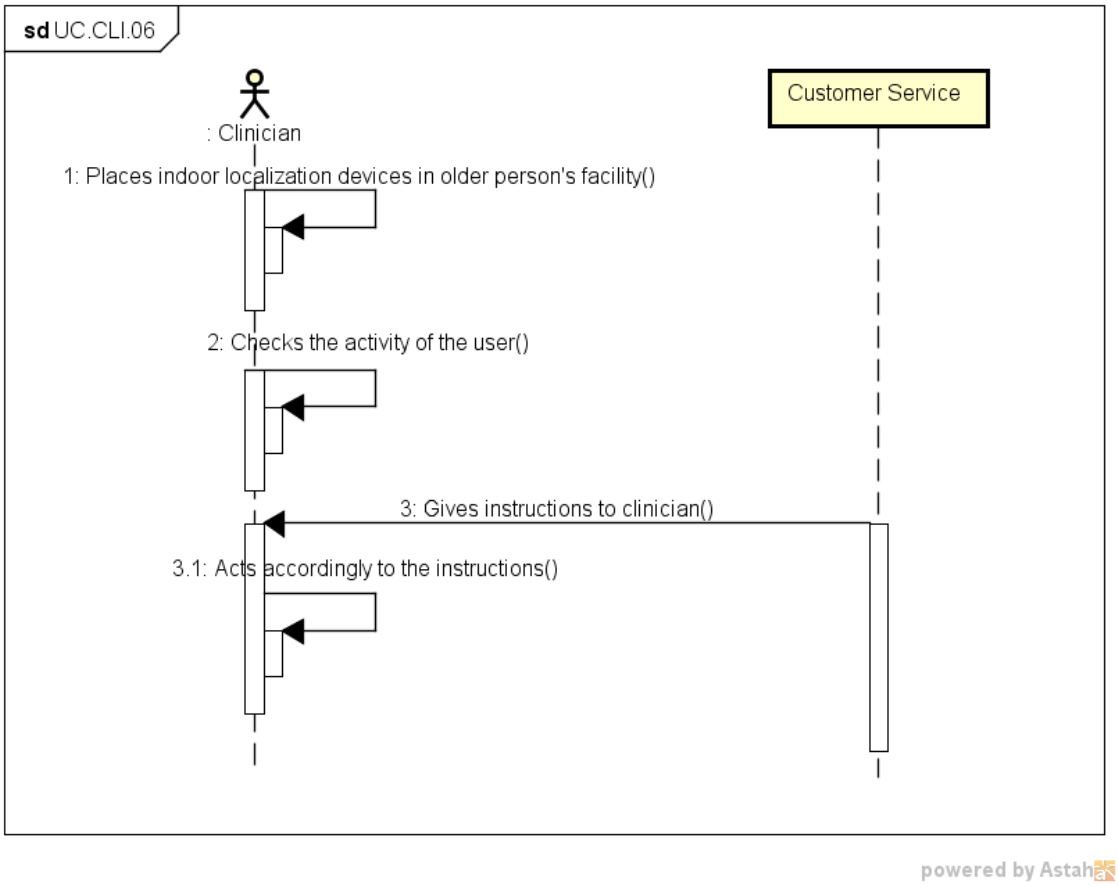


4.5.6 UC.CLI.06 – Indoor localization preparation - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.06 – Indoor localization preparation
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The clinician prepares the older person's home or other indoor facility, in order to be ready for indoor localization monitoring.
Assumptions & Pre-Conditions	• The clinician must place the indoor localization devices (e.g. beacons) in the appropriate places inside the house.
Goal (Successful End Condition)	• The indoor facility is ready for indoor localization.
Post-Conditions	• The positioning of the indoor localization devices is not obtrusive to the older person and his/her daily activities.
Involved Actors	• Clinician
Use Case Initiation	The use case is initiated when the clinician wishes to prepare a new facility for indoor monitoring.
Main Flow	1. The clinician places the indoor localization devices in the house 2. The clinician checks the activity of the user 3. The clinician acts accordingly to the customer service instructions.

Relationships with other Use Cases	UC.PAT.04
Specific Description	
Relevance to FrailSafe WPs	
Privacy & Regulation restrictions	The placed indoor localization devices should only record the older person's location.
Environmental restrictions	-
Quality of service indicators	The older person's location is recorded accurately.
References (optional)	-
Notes (optional)	-

UML Sequence Diagram

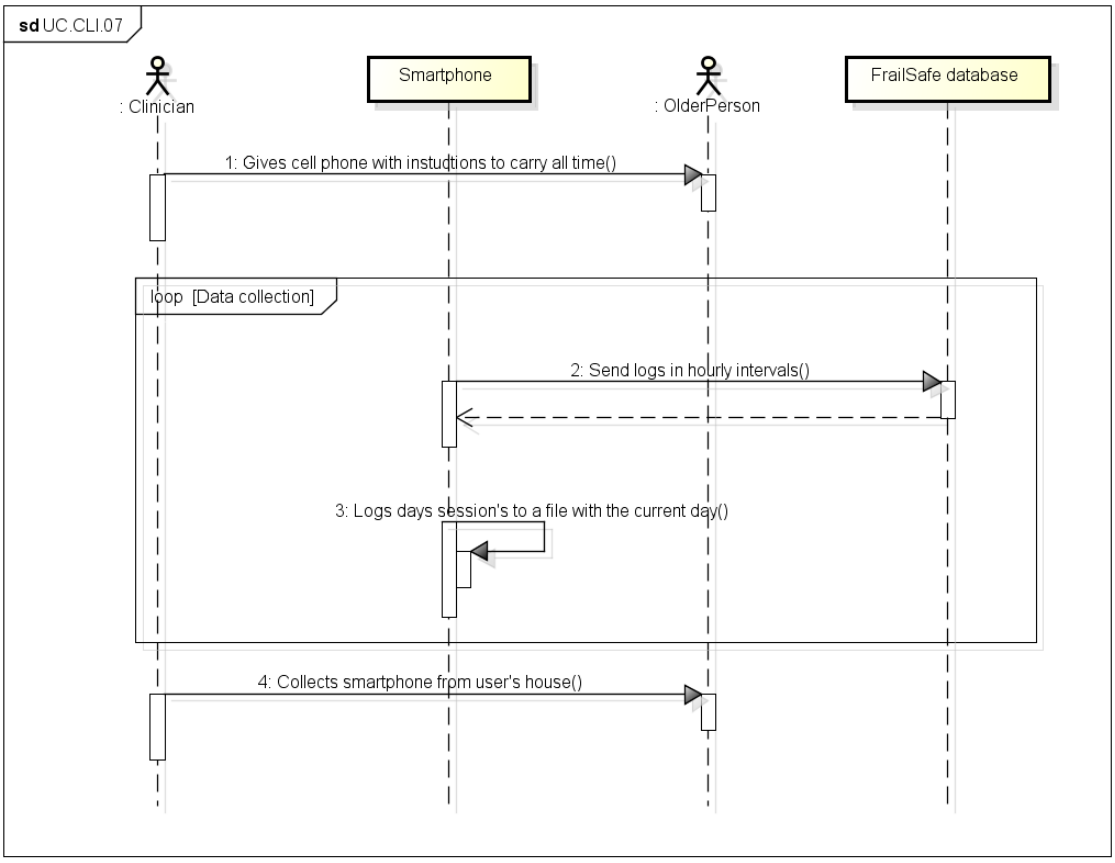


4.5.7 UC.CLI.07 – Outdoor localization preparation - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.07 – Outdoor localization preparation
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The Smartphone application Frailsafe GPS tracker is used to track and log the position of each user. It logs latitude, longitude and other location-specific measurements. The recorded data is auto uploaded via e-mail or FTP to remote servers, including a dedicated FTP server.
Assumptions & Pre-Conditions	• The FrailSafe GPS application must be installed on all smartphones • The user must enter the application and press the button 'start logging' and when finished the user must press the button 'stop logging' • No internet connection is needed • The user must carry the smartphone with him/her either in their pocket or in their bag. Indoor and outdoor activity is recorded.
Goal (Successful End Condition)	• To track and log the position of the person using it • To investigate how outgoing-social the person is • Possibility to count steps (suggestions from clinicians to include pedometer as well)
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	clinician
Use Case Initiation	The use case is initiated when the clinician gives specific instructions to the user for the use of the smartphone
Main Flow	1. The clinician gives the smartphone to the user with instructions to carry the smartphone with him/her on all times 2. The clinician collects the smartphone from the user's house 3. The application logs day's sessions to a file with the current date. 4. The application auto-sends logs in hourly intervals to chosen auto-send targets (which includes the Frail Safe FTP server, the custom FTP Server and e-mail address)
Relationships with other Use Cases	UC.PAT.05
Specific Description	

Relevance to FrailSafe WPs	
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	We receive very important information for their position, movement, social life and outdoor activity and indoor activity
References (optional)	-
Notes (optional)	-

UML Sequence Diagram



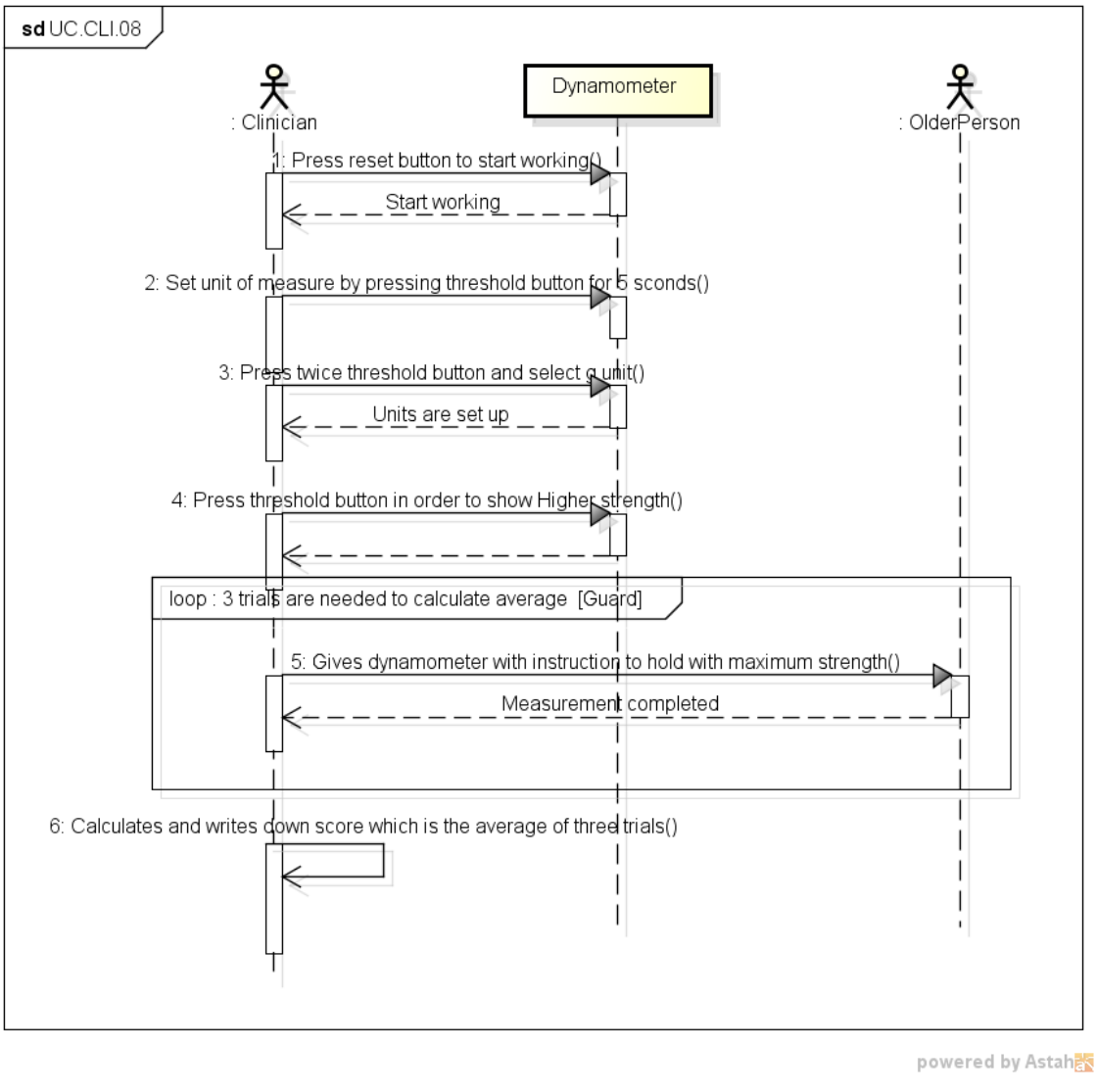
4.5.8 UC.CLI.08 – Dynamometer - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.08 – Dynamometer
Version	v0.1
Authors	CERTH, MATERIA

Last Update	December 2016
Brief Description	The dynamometer is used as part of the clinical assessment of the users to measure their grip strength. Later on, the dynamometer will also be used with the cognitive games for physical training, strength and also making the games more fun for the users.
Assumptions & Pre-Conditions	• The values of each user are very important, as the strength in the dynamometer test is one of Fried's criteria that is used to categorize the users in frail, non-frail, pre-frail.
Goal (Successful End Condition)	• Categorize the user in frail, non-frail, pre-frail.
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• clinician
Use Case Initiation	The use case is initiated when the clinician sets up the dynamometer and gives it to the user
Main Flow	1. The clinician must press the reset button in order for the dynamometer to start and press the reset button to stop working. If the clinician forgets to press the reset button to stop the dynamometer it stops on its own after 3 minutes. 2. It is very important to set the unit of measure on the dynamometer. The clinician can do this by pressing for 5 seconds the button 'threshold' and then pressing twice the button threshold and selecting the 'g' unit 3. The dynamometer has two screens. When pressing the button threshold two measurements are showed. H=high which is the higher strength of the user and L=low which is the lowest strength of the user. According to our project and Fried's criteria we need the H=high strength of the user. Next to H/L a number appears that are the seconds that the user was pressing the dynamometer. 4. The clinician gives the dynamometer to the user during the clinical assessment 5. The clinician instructs the user to hold the dynamometer with as much as strength possible. 6. The score of each user for the dynamometer test is calculated by calculating the average of 3 trials by the clinician 7. The clinician writes down the score
Relationships with other Use Cases	UC.PAT.06

Specific Description	
Relevance to FrailSafe WPs	
Privacy & Regulation restrictions	
Environmental restrictions	-
Quality of service indicators	We receive important information from the user's strength which is one of the five aspects of categorization according to Fried's criteria.
References (optional)	-
Notes (optional)	-

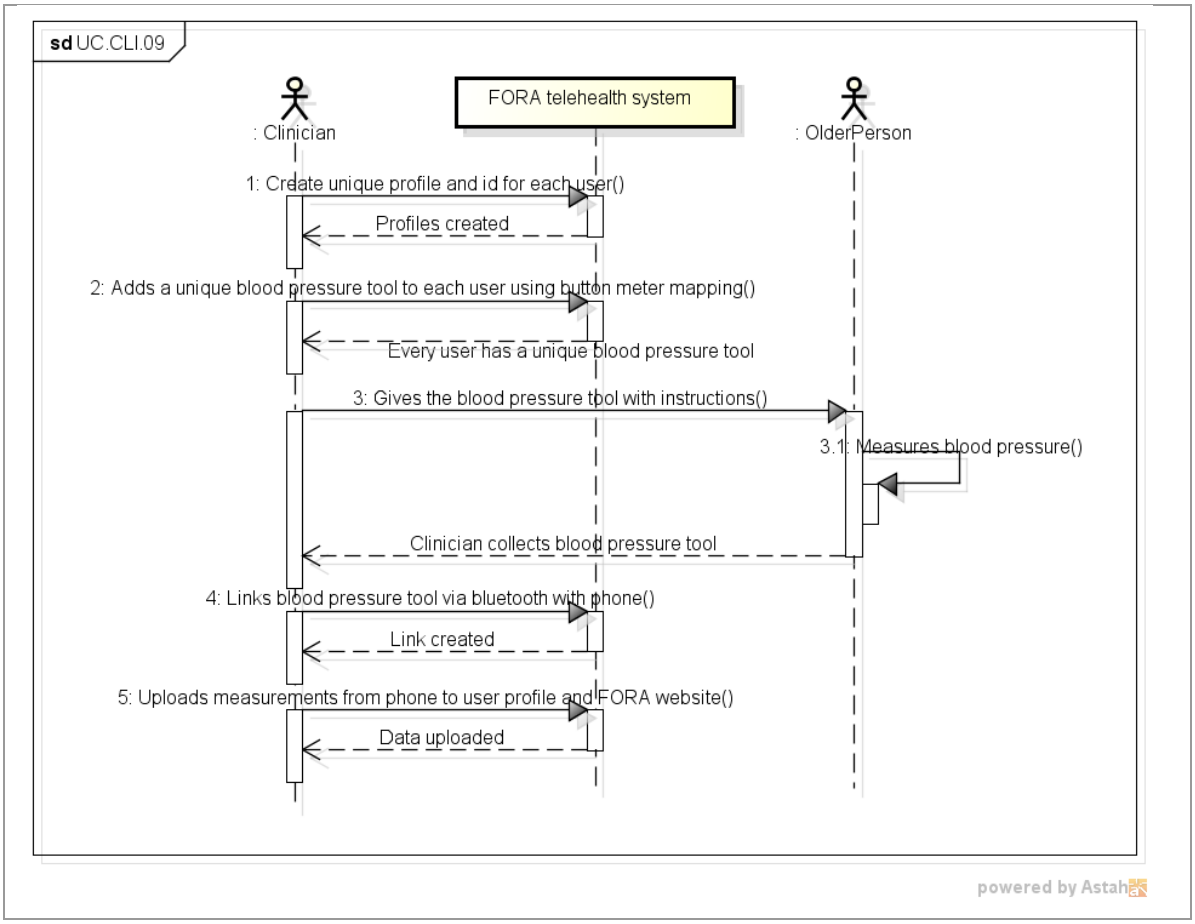
UML Sequence Diagram



4.5.9 UC.CLI.09 - FORA telehealth system - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.09 – FORA telehealth system
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The FORA telehealth system is a website where the clinician can create a unique profile for each user and have a medical history of each user stored online. In the case of the Frail Safe project, this system is linked with the FORA blood pressure tools that the users use at their home as part of their clinical frail safe assessment.
Assumptions & Pre-Conditions	• The clinician must create a unique profile and login details for each user • The clinician must link each user with a blood pressure tool by pressing the button 'meter mapping' when creating their profile and enter the unique serial number of the blood pressure tool. Only one blood pressure tool can be linked with a user at a time. When adding a new user, the previous blood pressure tool must be unlinked from the previous user in order to be linked to the new user. • The user must measure their blood pressure on their own at their home environment. • In order for the clinician to be able to synchronize the blood pressure tool with the FORA telehealth system, the Bluetooth of the blood pressure tools needs to be turned on in order for the readings of the blood pressure of each user to be uploaded to the FORA telehealth system. Also, the clinician needs to use the smartphone's FORA application by going to settings, telehealth service, upload.
Goal (Successful End Condition)	• To investigate any abnormalities in the blood pressure of the users • Possibility for the users to be trained to use a blood pressure at their home and not only for the project.
Post-Conditions	• The FrailSafe database is updated with new data.
Involved Actors	• clinician
Use Case Initiation	The use case is initiated when the clinician sets up an account for each user and gives the BP tool to the user with specific instructions on how to use it
Main Flow	1. The clinician creates the unique profile and unique login details of each user in the FORA telehealth system. 2. The clinician adds a unique blood pressure tool to the user by pressing the button 'meter mapping' in the profile of the user and adding the unique serial number of the blood pressure tool.

	3. The clinician gives the blood pressure tool to the user at their home with specific instructions 4. The blood pressure tool measures the blood pressure of the user 5. The clinician collects the blood pressure tool from the user's house. 6. The clinician links the blood pressure tool with the phone via Bluetooth and then uploads the measurements from the phone to the FORA website to the user's unique profile.
Relationships with other Use Cases	UC.PAT.06, UC.PAT.07
Specific Description	
Relevance to FrailSafe WPs	
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	We receive information regarding their blood pressure, an issue very important in ages 70+. We might be able to detect users with blood pressure issues and give them recommendations.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	



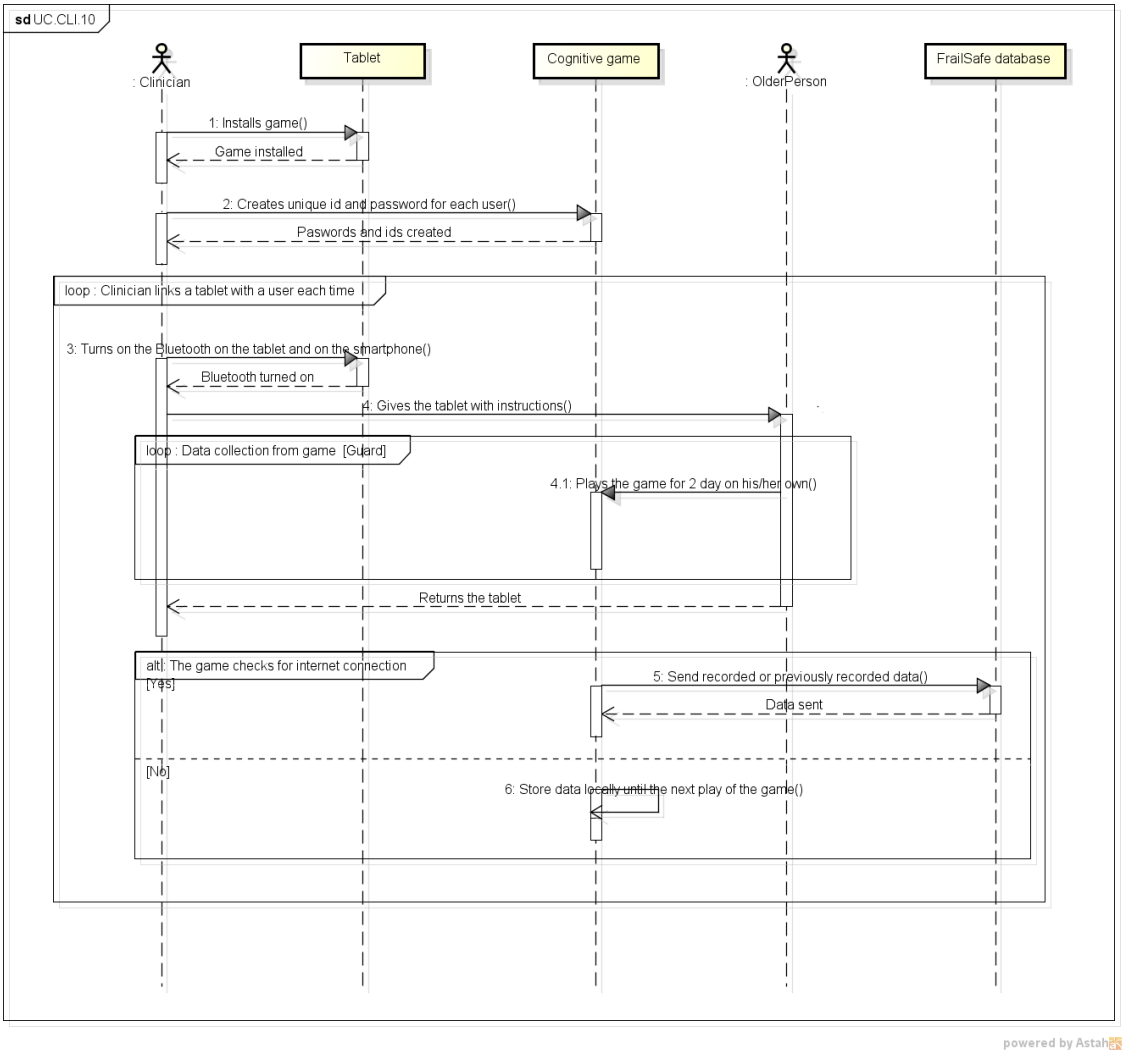
4.5.10 UC.CLI.10 - Cognitive game preparation - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.10 – Cognitive game usage
Version	v0.1
Authors	CERTH, SIGLA, MATERIA
Last Update	December 2016
Brief Description	The clinician prepares the cognitive games in order to be ready to be played by the older person.
Assumptions & Pre-Conditions	• The clinician must install the cognitive games on the user's tablet. • The clinician must create a unique id and password for each user beforehand. • The online FrailSafe cloud server should be running. • The FrailSafe central gateway needs to be running as it is linked with the transferring of data of the game on the tablet. • The Bluetooth of the smartphone and of the tablet needs to be turned on
Goal (Successful End Condition)	• To entertain and train the users • The clinician can monitor the users online by looking up

	their statistics that show performance, if the user is improving or declining over the period of time • The performance to the game is stored to the FrailSafe online server.
Post-Conditions	• The FrailSafe database is updated with new data. • The FrailSafe game suite is ready to initiate a new game session.
Involved Actors	• Clinician
Use Case Initiation	The use case is initiated when the clinician identifies the user, allocates the tablet and gives initial instructions.
Main Flow	1. The clinician installs the game on the tablet 2. The clinician creates a unique id and password for each user 3. The clinician links a tablet with a user each time 4. The clinician turns on the Bluetooth on the tablet and on the smartphone. 5. The clinician gives the tablet to the user with specific instructions on how to play the game 6. The clinician gives a specific timeline to the user, i.e. to play the game on their own for 2 days 7. The clinician collects the tablet from the user 8. The game checks for an Internet connection. 9. If an internet connection is on, the recorded data, and any previously recorded and unsent data, are transmitted to the FrailSafe online server. Otherwise, they stay stored locally, until the next playing of a game.
Relationships with other Use Cases	UC.PAT.10
Specific Description	
Relevance to FrailSafe WPs	WP5, WP4, WP6
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The recommended game features (difficulty level, tasks, etc.) are relevant to the frailty status of the user. The recorded data become available in the FrailSafe server at most after a week.

References (optional)	-
Notes (optional)	-

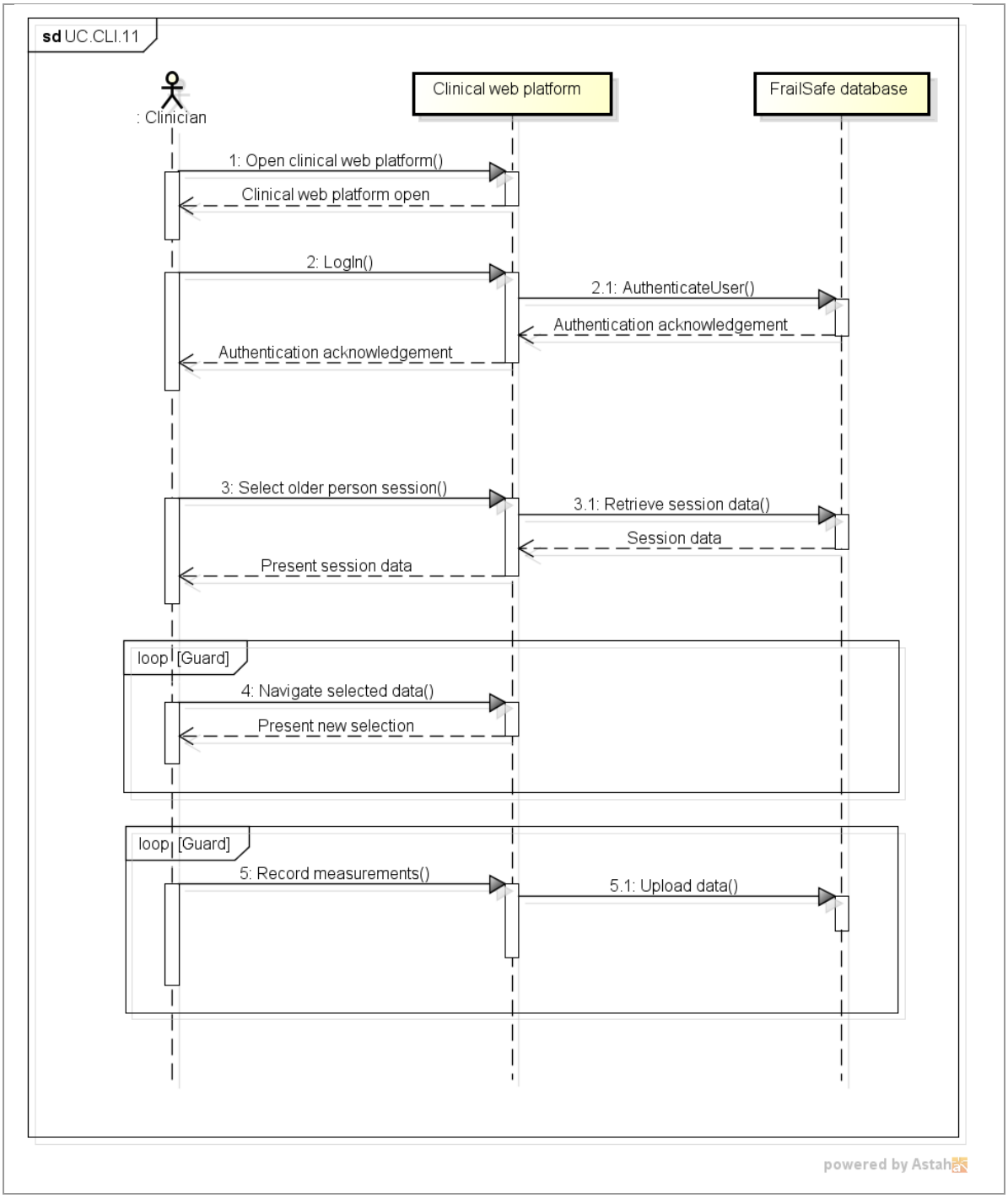
UML Sequence Diagram



4.5.11 UC.CLI.11 – Clinical web platform - [DP] [FP]

Generic Description	
Use Case Name	UC.CLI.11 – Clinical web platform
Version	v0.1
Authors	CERTH, SIGLA, MATERIA
Last Update	December 2016
Brief Description	The clinician uses the Clinical Web Platform to submit the clinical measurements for a patient session and view the data for a session.

Assumptions & Pre-Conditions	• The clinician must have an account for the Clinical Web Platform.
Goal (Successful End Condition)	• The submitted data are successfully uploaded to the FrailSafe database.
Post-Conditions	• The FrailSafe database is updated with new data. • The FrailSafe game suite is ready to initiate a new game session.
Involved Actors	• Clinician
Use Case Initiation	The use case is initiated when the clinician wishes to use the Clinical web platform to submit new session data.
Main Flow	1. The clinician opens the Clinical Web Platform. 2. The clinican logs in to the Clinical Web Platform. 3. The clinician uses the platform's interface to upload the data collected during a session with a patient. 4. The clinician uses the platform's interface to view the data that have already been collected.
Relationships with other Use Cases	UC.CLI.02
Specific Description	
Relevance to FrailSafe WPs	WP2, WP4, WP5
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
Environmental restrictions	-
Quality of service indicators	The submitted data are instantly uploaded to the FrailSafe database.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	


sd UC.CLI.11
: Clinician
Clinical web platform
FrailSafe database
1: Open clinical web platform()
Clinical web platform open
2: LogIn()
2.1: AuthenticateUser()
Authentication acknowledgement
Authentication acknowledgement
3: Select older person session()
3.1: Retrieve session data()
Session data
Present session data
loop [Guard]
4: Navigate selected data()
Present new selection
loop [Guard]
5: Record measurements()
5.1: Upload data()
powered by Astah

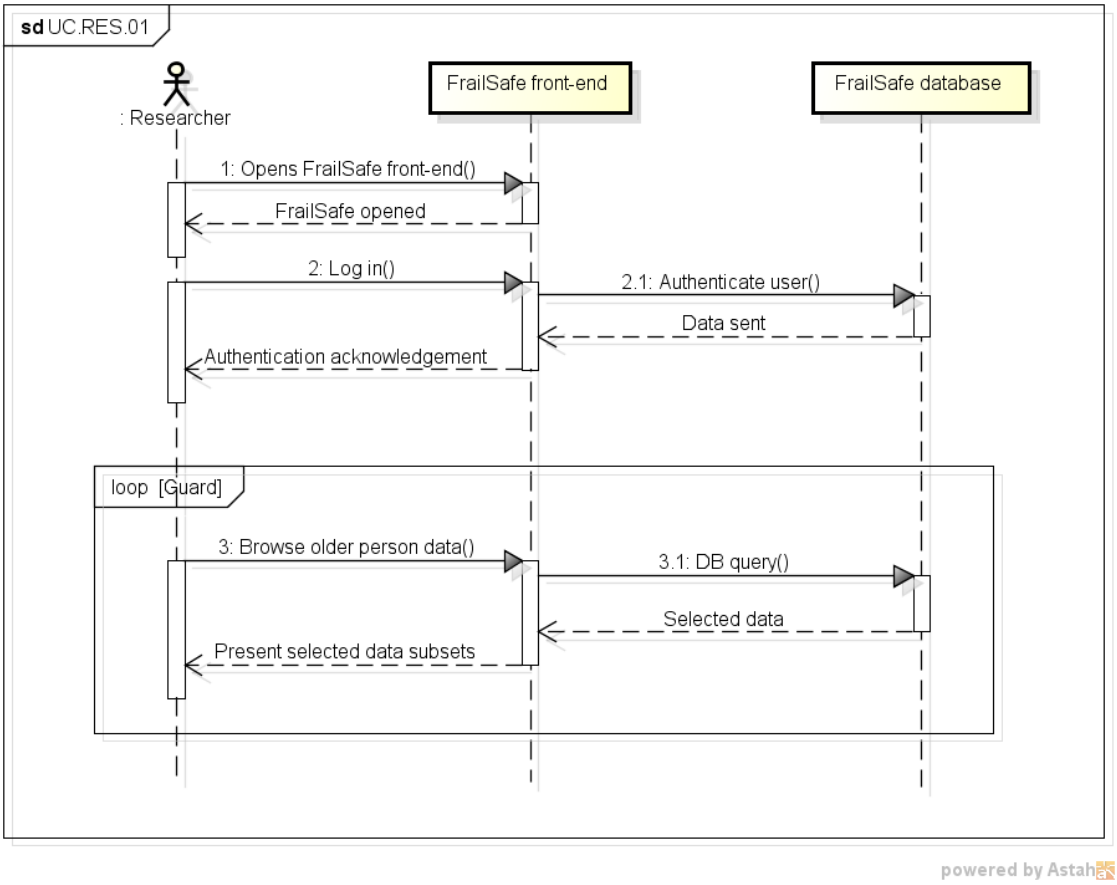
4.6 Researcher-oriented use cases

4.6.1 UC.RES.01 – Database browsing - [DP] [FP]

Generic Description	
Use Case Name	UC.RES.01 – Database browsing
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The researcher browses the FrailSafe database using FrailSafe front-end. The researcher can view the user data by exploring various available categorizations, e.g. by age, by blood pressure range, etc. The researcher can select a presented data subset for further analysis.
Assumptions & Pre-Conditions	• The researcher must have an account to the FrailSafe system.
Goal (Successful End Condition)	• The displayed data correspond to the categorization and sorting selected by the researcher.
Post-Conditions	• The FrailSafe database remains intact.
Involved Actors	• Researcher
Use Case Initiation	The use case is initiated when the researcher wishes to browse the available data, in order to select a subset for further analysis.
Main Flow	1. The researcher logs in to the FrailSafe front-end. 2. The researcher uses the front-end tools to browse the database, selecting data based on various categorizations and sorting/filtering them as desired. 3. The system presents the selected data subsets in the front-end, in a tabular format, so that the researcher can download the data as a file or analyze them with the visualization tools.
Relationships with other Use Cases	UC.RES.02, UC.RES.03, UC.RES.04
Specific Description	
Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The displayed data should be anonymized. Information linking the displayed data with a specific older person should be hidden from the researcher. The FrailSafe data should be available only to registered researcher users, in order to ensure their protection.
Environmental restrictions	-
Quality of service	The displayed data correspond to the data categorizations and

indicators	sorting options selected by the researcher. The system displays the requested data to the user within at most 3 seconds.
References (optional)	-
Notes (optional)	-

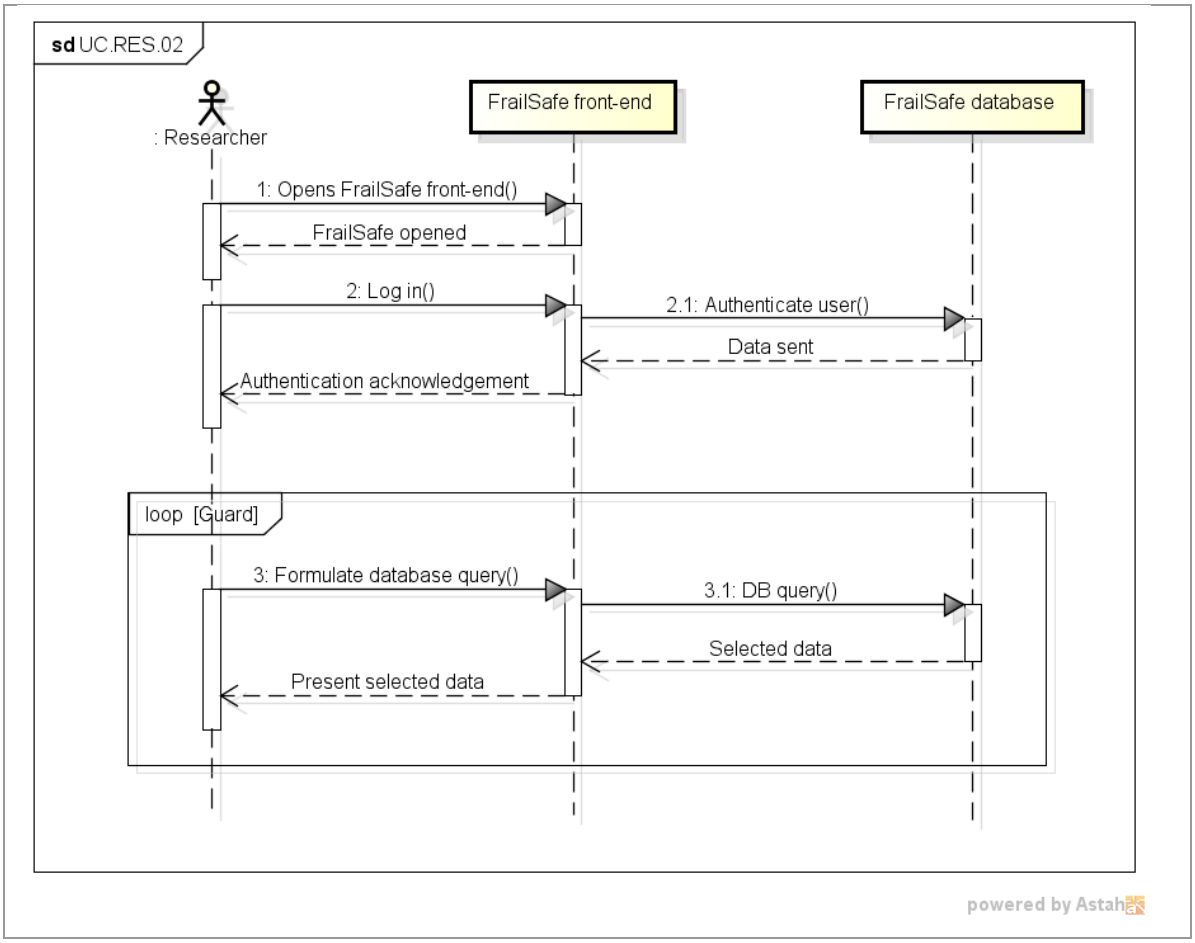
UML Sequence Diagram



4.6.2 UC.RES.02 – Database querying - [DP] [FP]

Generic Description	
Use Case Name	UC.RES.02 – Database querying
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The researcher formulates a data retrieval query using the FrailSafe front-end. The researcher can query the data of users having specific characteristics, e.g. within a specific age range, with increased blood pressure, etc., and combinations of them. After submitting the query, the system returns the desired data.

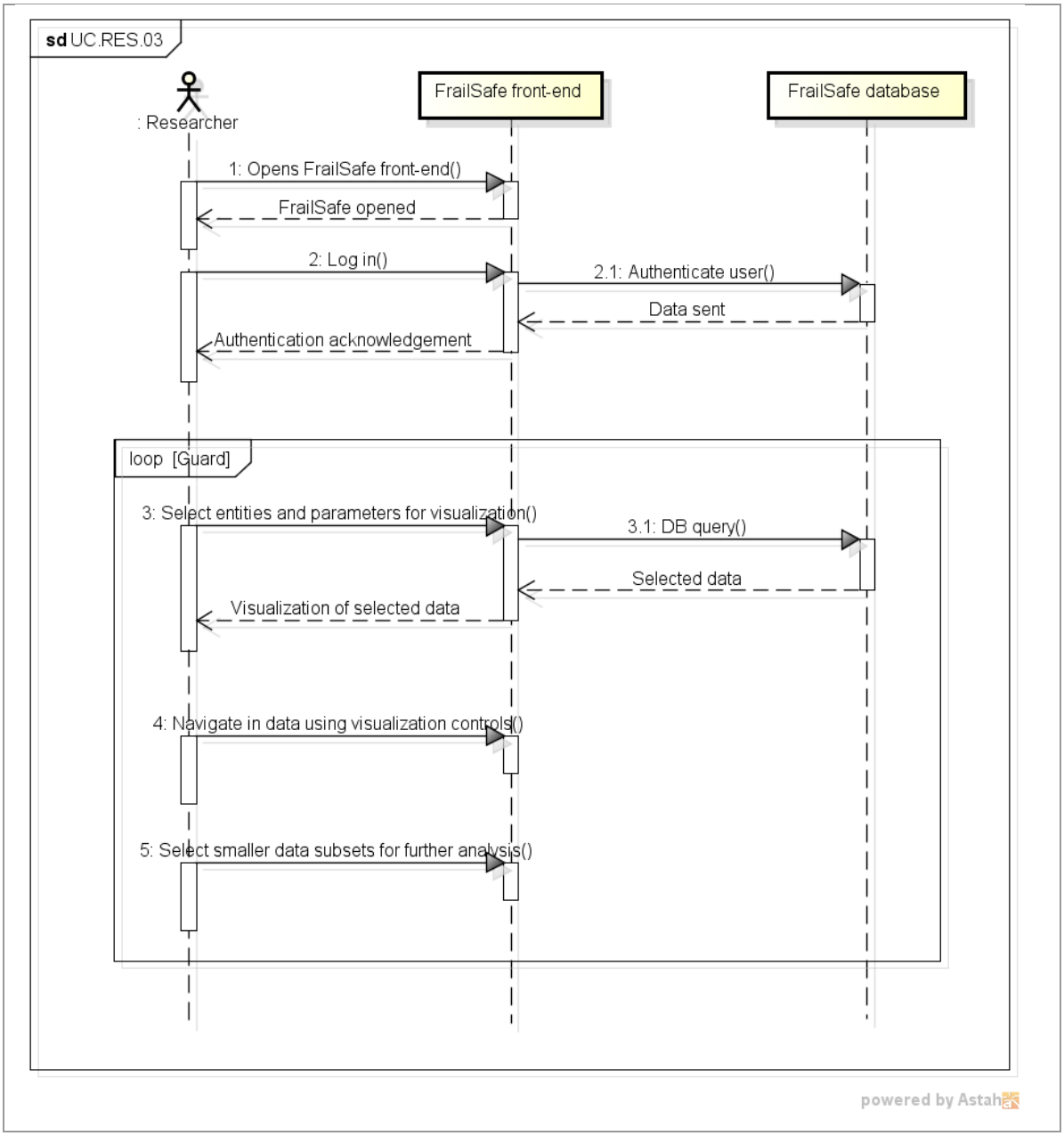
Assumptions & Pre-Conditions	• The researcher must have an account to the FrailSafe system.
Goal (Successful End Condition)	• The requested data subset is returned successfully.
Post-Conditions	• The FrailSafe database remains intact.
Involved Actors	• Researcher
Use Case Initiation	The use case is initiated when the researcher wishes to retrieve a specific subset of the FrailSafe data in order to work with.
Main Flow	1. The researcher logs in to the FrailSafe front-end. 2. The researcher uses the front-end tools to formulate a database query. 3. The researcher submits the query. 4. The system presents the results of the query to the researcher in the front-end, in a tabular format, so that the researcher can download the data as a file or analyze them with the visualization tools.
Relationships with other Use Cases	UC.RES.01, UC.RES.03, UC.RES.04
Specific Description	
Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The retrieved data should be anonymized. Information linking the displayed data with a specific older person should be hidden from the researcher. The FrailSafe data should be available only to registered researcher users, in order to ensure their protection.
Environmental restrictions	-
Quality of service indicators	The returned data correspond to the query parameters set by the researcher. The system retrieves the requested data to the user within at most 5 seconds.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	



4.6.3 UC.RES.03 – Visual analytics - [DP] [FP]

Generic Description	
Use Case Name	UC.RES.03 – Visual analytics
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The researcher uses the visual analytics tools of FrailSafe to analyse a selected subset of data. The user can select features and entities to visualize, combine multiple features and assign different weight to different parameters. The system visualizes the selected data and entities using graph-based visualization methods. The user can use these visualizations to find common patterns and clusters among the data. The user can navigate in the visualization by panning, zooming and selecting smaller subsets for further visualization.
Assumptions & Pre-Conditions	• The researcher must have an account to the FrailSafe system. • The researcher mush have already logged in to the FrailSafe system. • The researcher must have already selected a data subset for visualization, either through browsing (UC.RES.01) or

	query submission (UC.RES.02).
Goal (Successful End Condition)	• The displayed data correspond to the features and parameter combinations selected by the researcher.
Post-Conditions	• The FrailSafe database remains intact.
Involved Actors	• Researcher
Use Case Initiation	The use case is initiated after the researcher has selected a data subset (using either browsing or query submission) and he/she wishes to visualize the available data for further analysis.
Main Flow	1. The researcher uses the front-end visualization tools to select the entities and parameter combinations to visualize. 2. The system presents the selected data subsets in the front-end, visualizing the selected entities and parameters using graph-based visualization methods. 3. The researcher navigates through the visualized data using panning and zooming functionalities. 4. The researcher selects a smaller subset of the visualized data (e.g. a cluster) for further analysis and visualization.
Relationships with other Use Cases	UC.CLI.02, UC.CLI.04, UC.RES.01, UC.RES.02, UC.RES.04
Specific Description	
Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The displayed data should be anonymized. Information linking the displayed data with a specific older person should be hidden from the researcher. The FrailSafe data should be available only to registered researcher users, in order to ensure their protection.
Environmental restrictions	-
Quality of service indicators	The visualized data correspond to the entities and parameter combinations selected by the researcher. The visualized data are presented to the user within at most 3 seconds. The navigation through the visualized data is responsive in real time.
References (optional)	-
Notes (optional)	-
UML Sequence Diagram	

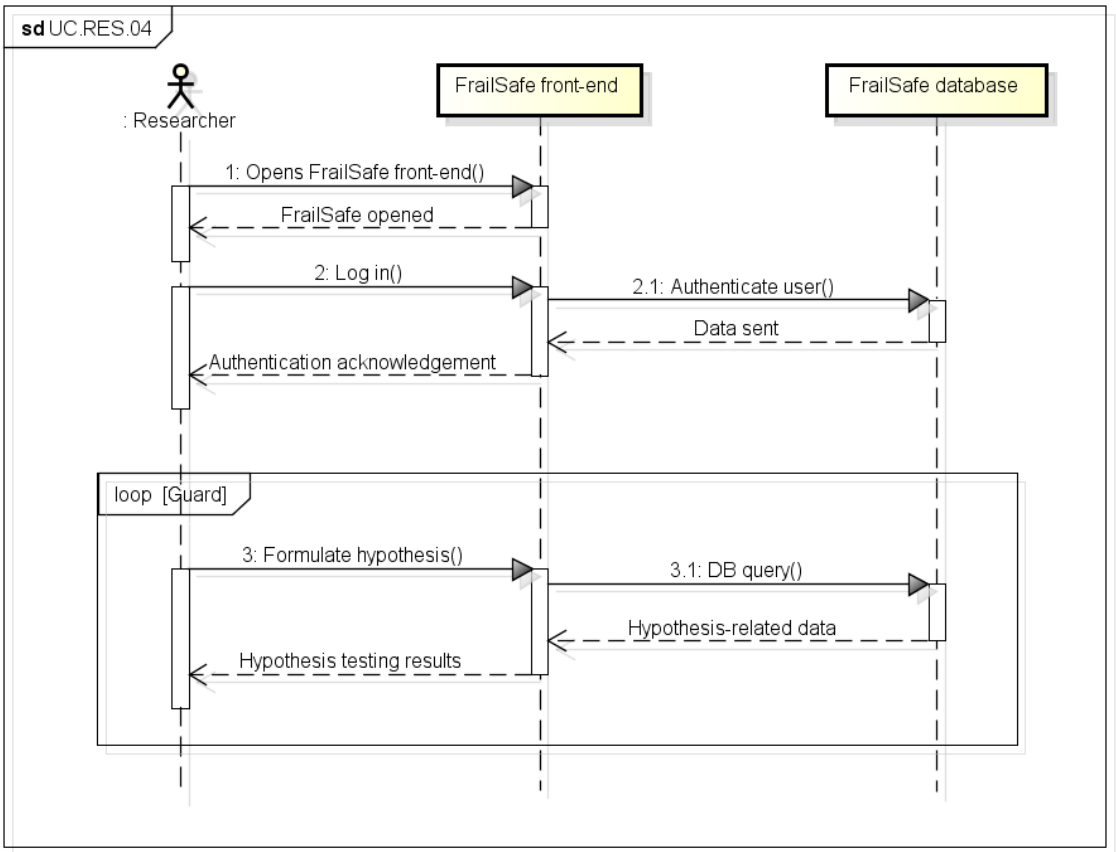


4.6.4 UC.RES.04 – Hypothesis testing - [DP] [FP]

Generic Description	
Use Case Name	UC.RES.04 – Hypothesis testing
Version	v0.1
Authors	CERTH, MATERIA
Last Update	December 2016
Brief Description	The researcher uses the hypothesis formulation and validation tools of FrailSafe verify specific hypotheses about a selected subset of data. The system uses underlying data analysis techniques or displays extra visualized information in order to assist the researcher in verifying or rejecting the formulated hypothesis.

Assumptions & Pre-Conditions	• The researcher must have an account to the FrailSafe system. • The researcher mush have already logged in to the FrailSafe system. • The researcher must have already selected a data subset for visualization, either through browsing (UC.RES.01), query submission (UC.RES.02), or visualization (UC.RES.03).
Goal (Successful End Condition)	• The hypothesis testing results correspond to the specific data subset and the specific hypothesis formulated by the user.
Post-Conditions	• The FrailSafe database remains intact.
Involved Actors	• Researcher
Use Case Initiation	The use case is initiated after the researcher has selected a data subset (using either browsing, query submission or visualization) and he/she wishes to test various hypotheses regarding the selected data.
Main Flow	1. The researcher uses the front-end hypothesis formulation tools to formulate a specific hypothesis about the selected data. 2. The user submits the formulated hypothesis to the system. 3. The system presents the results of hypothesis testing, either numerically or visually, depending on the nature of the submitted hypothesis.
Relationships with other Use Cases	UC.RES.01, UC.RES.02, UC.RES.03
Specific Description	
Relevance to FrailSafe WPs	WP4, WP5
Privacy & Regulation restrictions	The displayed information and results should be anonymized. Information linking the displayed data with a specific older person should be hidden from the researcher. The FrailSafe data should be available only to registered researcher users, in order to ensure their protection.
Environmental restrictions	-
Quality of service indicators	The results of hypotheses correspond to the data subset selected and to the specific hypothesis formulated by the user. The results of hypothesis testing are presented to the user within at most 3 seconds.
References (optional)	-
Notes (optional)	-

UML Sequence Diagram



4.7 FrailSafe evaluation protocols

A selection of some indicative use cases from the ones presented above will be used for the definition of the scenarios to be used for pilot testing during the evaluation phase of the project. All indicative use cases will be finalised in deliverable D7.1 It is important that specific ethics and safety protocols are followed during the execution of the scenarios, in order to ensure that all related regulations are followed. Evaluation protocols to be used are directly connected to the outputs of Deliverable D9.9 “Ethics, Safety and mHealth Barriers (regulation, legislation, etc.) Manual”. The evaluation procedures used will comply with the plan proposed in this deliverable. They will also contribute to the deliverable with new privacy, safety or ethical requirements, if such may arise during the timeline of the project.

All evaluation procedures will be conducted in agreement with the above FrailSafe ethics manual. The manual incorporates all relevant national and international European conventions. This will allow the identification of the key ethical and legal issues arising in the execution of the evaluation scenarios, so that they are resolved. The data that are essential for the project will also be separated from those that are not essential and should be excluded from retention. All project deliverables will be scanned for compliance with the ethics manual. In order to assist in this procedure, an experienced ethics supervisor, provided by INSERM, was established in the early stages of the project, in order to act as the project’s Ethics Advisory Board. The role of the ethics supervisor is to examine all relevant issues and train the partners and participants on how to conform to the recommendations included in the Ethics Manual.

The legislation barriers for the adaptation of the FrailSafe components will also be examined, including regulatory issues (security, medical devices, mHealth interfaces), legislation frameworks, policy issues (older person empowerment, reimbursement) and GSMA (Policy and Regulation for Innovation in Mobile Health, 2012).

4.7.1 Ethics

All medical research conducted by the clinical partners of FrailSafe will receive ethical approval by the respective national ethics committees (Greece, Cyprus and France). The ethics committees will review all research applications and ensure that the tasks required by the participants are acceptable. The committees will also review all relevant documentation regarding participant information, such as older person information sheets, consent forms, surveys, etc., in order to ensure that the participants have been sufficiently informed to help them decide whether they wish to participate in the study or not.

4.7.2 Data management

The data collected throughout the project will be handled appropriately according to standard operational procedures (SOPs). The participant's data will be anonymized, by only using subject's initials and unique trial numbers for identification. Data encryption techniques will be used while transferring data between devices. Hard copies of all consent forms, clinical research files and paper surveys and questionnaires will be securely stored in locked cabinets at the responsible host institutions. Electronic data will be stored in the FrailSafe servers and cloud. Access to the data will be password-protected. Study documentation will be archived and subject to audit for at least 15 years, as is required by clinical practice. Data transparency will meet clinical EU regulations. More details about the data management plan can be found in Deliverables D8.12, D8.13 and D8.14.

4.7.3 Patient safety

In order to ensure the rights, safety and wellbeing of the participants in the FrailSafe project, a written informed consent will be obtained from all involved older persons. Researchers and partners will explain with clarity the rationale of conducting the survey, the exact procedure which will be followed to conduct the survey and which are the expected outcomes. It will be stated clearly that the older persons are under no obligation to consent and that their consent will be carried out before any procedure of the survey is initiated. Potential participants will be offered as much time as they need in order to be completely informed for their decision. This may involve having time alone in order to read carefully the supplied information sheet and/or discussing any emerging questions with the researcher. The participants have the right to refuse to enter the study, as well as the right to exit at any time after they have started, without providing any reasons and without prejudicing further treatments. A copy of the signed informed consent will be given to the participant, while the original will be stored at the study site.

5 FRAILSAFE USER CENTERED DESIGN METHODOLOGY

5.1 Introduction

User Centered Design (UCD) is defined as an interactive approach of system development that focuses specifically on the system's usability and usefulness. It is a development approach that focuses on the end users that will ultimately come to use the product or service created [8][9]. UCD methodologies are used throughout the specification of end-user requirements, the design and development of software prototypes and the implementation of evaluation activities.

The aim of UCD methodologies is to form a strong link between intended user groups and technology developers based on the continuous iteration of analysis, design and evaluation steps throughout the timeline of a project [10][11][12]. It is based on the idea that the product/service developed should suit the user, rather than making the user suit the product/service. Furthermore, UCD aims to examine whether the user requirements have been sufficiently met or further enhancements of the software tools and proposed processes are required.

5.2 Methods for User Centered Design

In this section, a summary of the most important methodologies for UCD, which are related to the goals of the FrailSafe project, will be presented. In order to better describe their positioning in the different stages of development the reviewed methods have been separated into three main categories:

- Assessment of user feedback
- User-assisted design
- User-assisted implementation

In the following sections, representative methods to accomplish the goals of each category are briefly presented.

5.2.1 Methods for user feedback assessment

The aim of user feedback assessment is the collection of user feedback and the examination of its relevance to the objectives and the workplan of the FrailSafe project. Methods for user feedback assessment include the following:

- **Questionnaires**: A questionnaire is a set of questions that are defined and sorted in order to allow the objective and accurate collection of user responses and their translation to useful and statistically significant information. Phases of the preparation and the deployment of questionnaires: definition of the questionnaire's objective, definition of the potential user groups and questionnaire participants, formation of the questionnaire, deployment of the questionnaire, analysis of the results. Types and indicative examples of questions: General questions, open questions, scalar questions, multiple choice questions, ordered questions.
- **Interviews**: The interview is a method to understand the unique point of view of a participant through the face-to-face interaction with an interviewer. The preparation and deployment of interview: The selection of questions should be also done in such a way that will allow participants to answer truthfully to the interviewer, the location to carry out the interviews can vary and should ideally be a neutral location that offers privacy, especially when sensitive medical data will be discussed. The questions should be written down in advance and as a form of a discussion plant that can help the interviewer direct the interview in the appropriate area and do not deviate from its main objective. Interviewers

may use recording devices in addition to their written notes in order collect a more detailed record of participant responses.

- **Surveys**: They are aiming to collect quantitative data that the participants can provide irrespectively of the details of the specific project. The planning of the survey should be based on the following pillar components: Definition of the targeted users before you composition of the questions, identification the method that will be used to distribute the surveys based on the identification of the optimal characteristics for the specific application, a careful study of the characteristics of the user groups will allow the identification of issues that may lead to the exclusion of an important percentage of the population, careful selection of the time period that the survey will be deployed, the design of the survey should include the conditions that will indicate its completion.
- **Contextual inquiries**: They are used in order to assess information from the real life environments of the representative users so as to better understand their needs and requirements. They should be based on a number of basic components: the users should be informed regarding the whole process and their written consent should be obtained, the researchers should study carefully whether the inquiry will be based on active or passive observation.
- **Focus groups**: In this method, users are asked to share their opinions, thoughts and ideas about a specific subject and discus their views towards a conclusion that can express the majority of participants. Steps: the moderator should introduce the topic of the discussion and explains the participants what is expecting to get out from this process, the moderator should start addressing some questions to the participants in order to start the discussion process.
- **Task analysis**: This method is essential when it is required to analyse in detail the user actions, and is particularly useful for the design of decision support systems as they are foreseen by FrailSafe. Two main methodologies that can be applied within the task analysis method are: 1. the use of the hierarchical task analysis where tasks or high level are decomposed in simpler ones, detailing the components and the sequences among them, 2. the use of a flow chart, using which a sequence of actions from the user's point of view is presenting associating inputs and outputs. The main pillar components of the task analysis of users are the understanding of triggers, the understanding of the use cases and the understanding of the goals of the project.

5.2.2 Methods for user-assisted design

The aim of user-assisted design is the understanding of the opinions and suggestions of participants to specific design decisions as they will be used to form the actual final product. Methods for user-assisted design include the following:

- **Participatory design**: The users are asked to cooperate for the design of a prototype using different approaches and following different goals as they are set by the researcher.
- **Co-discovery**: a type of usability testing where two participants attempt to perform tasks together while being observed.
- **Prototyping**: the collection of user feedback based on a prototype version that is produced during the initial stages of development. The most important and commonly used concepts: Rapid Prototyping, Reusable Prototyping or Evolutionary Prototyping, Modular Prototyping or Incremental Prototyping, Horizontal Prototyping, Vertical Prototyping, Low-fidelity Prototyping, High-fidelity Prototyping.
- **Storyboarding**: it is based on the use of images demonstrating an interactive sequence that represent the behavior of the system, then users are asked to order the images so they describe a useful and easy-to-use interface.

- **Card sorting**: it consists from number of descriptions of concepts separated (cards) that the participants are asked to categorise according to their characteristics or relations.

5.2.3 Methods for user-assisted implementation

The aim of user-assisted implementation is the involvement of the participants in the actual development processes and the increase of their understanding regarding the development problems and barriers that can affect possible design decisions. Methods for user-assisted implementation include the following:

- **Expert review**: it is used to collect feedback and specific suggestions from experts based on their experience in the implementation of similar solutions.
- **Usability testing**: it evaluates an application based on the collection of data during the use of the system by actual users and optimally in the intended real world environment.
- **Heuristic evaluation**: it focuses on the understanding of usability issues of a system, based on the input of a small group of expert evaluators with experience in Human Computer Interaction. Steps: the definition of the system's interaction flow and the accurate description of the intended scope of the session, the evaluators can focus their analysis on specific interaction elements and provide their feedback, recommendations and concerns, the group of all the evaluators should discuss the results of their analysis.
- **Think aloud protocol**: participants are asked to describe their thinking process verbally in order to reveal their thoughts, feelings and opinions while interacting with system under evaluation.
- **Performance measurements**: it focuses on the assessment of quantitative metrics of the performance of various system components.
- **Log file analysis**: the automatic storing of user-system interactions and their subsequent analysis for the identification of usage patterns as well as potential problems in usability.
- **Feature / Consistency / Standards inspection**: it analyzes specific characteristics of a system and they are usually based on use case scenarios.

5.3 UCD methodology for FrailSafe

The User Centered Design methodology to be used within the FrailSafe project should ensure that the requirements of the users, both regarding functionalities and quality issues, are met. In any large project involving user participation, the types of requirements that should be fulfilled by the project form a hierarchy, as depicted in Figure 13. The requirements for the actual functionalities of the system and its utility should always be based upon the preservation of high standards of ethical requirements and the safety of system users. Provided that these basic requirements are met, considerations regarding the usability of the system components and their desirability as products should be made.

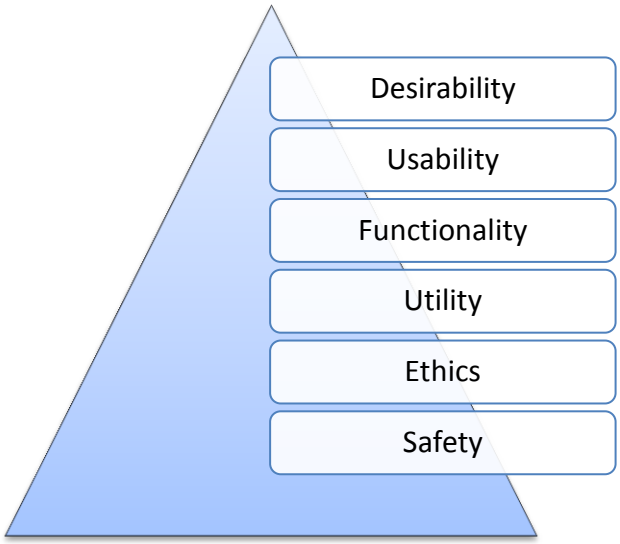


Figure 13: Hierarchy of requirement types.

The UCD methodology of FrailSafe is intended to involve all the different types of users targeted by the project objectives and also collect the feedback from experts in the medical field, technology developers and commercial entities in order to support the different tasks of the project. In detail the following groups can be involved in the UCD processes:

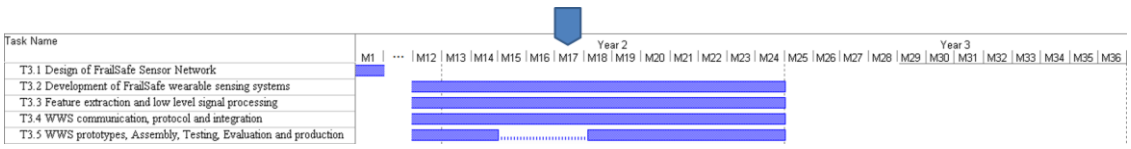
- Older people
- Families of older people
- Healthcare professionals
- Researchers
- Commercial organisations
- Technology developers

During the course of the project, representative users from the above categories are planned to use the system components and, at specific times, to be employed in order to provide feedback regarding their use. The feedback acquisition procedure will be focused on those components of the FrailSafe system which are exposed to end users:

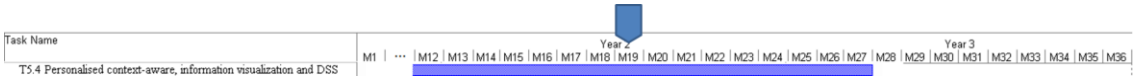
- The FrailSafe sensor network and wearable sensing system,
- The personalized information visualization and decision support system,
- The FrailSafe game suite, and
- The integrated FrailSafe system

The UCD methodology planned to be followed for each of the above components is presented in more detail in the following tables. For each component, the types of end-users to participate are listed, along with the UCD methods planned to be used and an indicative time schedule for the feedback collection.

5.3.1 UCD plan for the sensor network and wearable sensing system

Component	Sensor network and wearable sensing system
Description	This component includes the whole network of sensors that will be used for the older person monitoring and the data acquisition. It involves physical state sensors, such as the heart rate monitoring, respiration monitoring, posture monitoring, accelerometers, etc, embedded in the WWBS, as well as indoor and outdoor activity monitoring sensors. Although not “sensors” in the strict sense, this component also includes the use of measurement devices, such as the dynamometer, blood pressure monitor, scales and Mobil-o-graph.
Involved participants	• Patients: Their feedback involves important aspects such as acceptance, usability, ease of use, obtrusiveness, etc. • Healthcare professionals: Their feedback involves aspects such as usefulness, safety, ethics, ease of installation, ease of monitoring, ease of data collection, etc. • Commercial organizations: Their feedback involves aspects such as market acceptance and exploitation as products in similar or different applications. • Technology developers: Their feedback involves aspects such as innovation, possible technological advancements, etc.
Potential UCD methods to use	• Questionnaires • Interviews • Online surveys • Focus groups • Prototyping • Expert review • Usability testing • Feature/Consistency/Standards inspection
Indicative schedule	
M17 	

5.3.2 UCD plan for the personalized information visualization and DSS

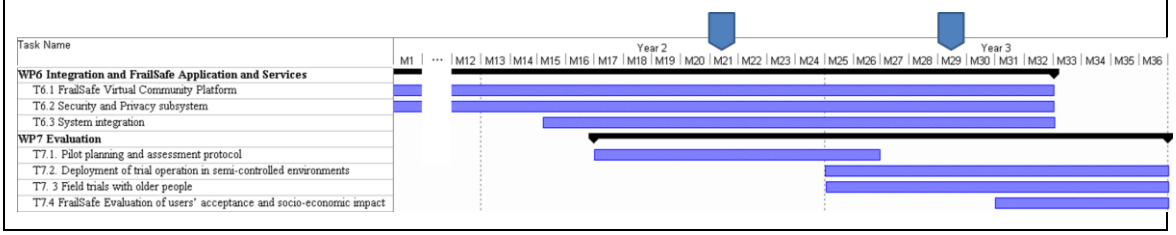
Component	Personalized information visualization and DSS
Description	This component includes the information visualization modules, targeted both to the older person, with simple and intuitive visualizations of personal information, as well as to the healthcare professional, with more elaborate visual analytics methods. It also includes the Decision Support System module, aimed to assist the healthcare professional in providing suggestions to the older persons.
Involved participants	• Patients: Their feedback involves aspects such as usability, usefulness, ease of use, suggestions for advancements, etc. • Healthcare professionals: Their feedback involves aspects such as usefulness, ease of use, privacy, etc. • Researchers: Their feedback involves aspects such as usefulness, usability, ease of learning, etc., mostly with regard to the visual analytics methods. • Commercial organizations: Their feedback involves aspects such as market acceptance and exploitation as products in similar or different applications. • Technology developers: Their feedback involves aspects such as innovation, possible technological advancements, etc.
Potential UCD methods to use	• Questionnaires • Interviews • Online surveys • Focus groups • Prototyping • Expert review • Usability testing • Performance measurements • Log file analysis • Feature/Consistency/Standards inspection
Indicative schedule	
M19 	

5.3.3 UCD plan for the game suite

Component	Game suite
Description	This component includes the whole FrailSafe game suite. The game suite includes games aiming to both assess and train the older persons in terms of both physical and cognitive skills. The games employ interaction with devices such as the tablet, the AR glasses, the dynamometer, the IMUs, etc.
Involved participants	• Patients: Their feedback involves aspects such as usability, usefulness, safety, ethics, ease of use, ease of learning, desirability, suggestions for advancements, etc. • Healthcare professionals: Their feedback involves aspects such as usefulness, safety, ethics, ease of installation, ease of learning, etc. • Commercial organizations: Their feedback involves aspects such as market acceptance and exploitation as products in similar or different applications. • Technology developers: Their feedback involves aspects such as innovation, possible technological advancements, etc.
Potential UCD methods to use	• Questionnaires • Interviews • Online surveys • Focus groups • Prototyping • Expert review • Usability testing • Log file analysis • Feature/Consistency/Standards inspection
Indicative schedule	
M17	

5.3.4 UCD plan for the integrated FrailSafe system

Component	Integrated FrailSafe system
Description	The integrated FrailSafe system will also be considered as a whole in the UCD methodology. The goal is to collect feedback about the functionality of the system as a whole, on the communication among the individual parts of the system and on the performance of complete usage scenarios. The feedback collected with regard to both the individual components, as in the above tables, and the integrated system is also going to be used for the systematic evaluation of the system.
Involved participants	• Patients: Their feedback involves aspects such as acceptance, usefulness, usability, safety, ethics, ease of learning, desirability, suggestions for advancements, etc. • Healthcare professionals: Their feedback involves aspects such as usefulness, usability, safety, ethics, performance, ease of installation, ease of learning, etc. • Researchers: Their feedback involves aspects such as usefulness, usability, performance, ease of learning, etc. • Commercial organizations: Their feedback involves aspects such as market acceptance and exploitation of the whole system in similar or different applications. • Technology developers: Their feedback involves aspects such as innovation, possible technological advancements, etc.
Potential UCD methods to use	• Questionnaires • Interviews • Online surveys • Focus groups • Prototyping • Expert review • Usability testing • Performance measurements • Log file analysis • Feature/Consistency/Standards inspection
Indicative schedule	
M21, M29	



6 CONCLUSIONS

The aim of the current deliverable was to act as a guide for the development of the FrailSafe system, so that it is centered around the actual needs and requirements of the end-users. It is important to engage the opinions of end users throughout the design and implementation phases of the project, in order to ensure that the project's objectives are met and the development does not deviate from actual user needs.

In the beginning of this deliverable, the target user groups of the FrailSafe system were identified:

- Older persons
- Families of older persons
- Medical healthcare professionals
- Researchers

In order to collect the needs of these user groups from FrailSafe, feedback collection campaigns have been designed and executed. Focus groups, surveys and interviews of older persons, their families and clinicians have been conducted. The collected feedback indicated a positive feeling of all users towards the goals of FrailSafe and provided an insight into the general requirements of users from such as system, which can be summarized to the following:

- Improved understanding of frailty
- Individualized help and monitoring
- Enjoyable frailty-preventing activities
- Predictive treatment functionalities and real-time alerts
- Unobtrusive and easy to use sensory components
- Easy to use and learn software components
- Extensive data collection for research

Based on these requirements, the specific use cases of FrailSafe were designed. The use cases are scenarios of usage of the various FrailSafe components, illustrating how they should perform and communicate with each other. The project's use cases were split into four groups, one for each of the target user types. A total of 27 use cases were designed. A detailed report was provided for each use case, including a step-by-step flow of actions.

The designed use cases will in turn be the basis for the design of the pilot trials during the evaluation period of the project. For this reason, following the use case definition, the current deliverable also contained an account on the evaluation protocols that will be followed, ensuring safety and ethics requirements throughout all user studies.

Finally, a report on the FrailSafe User Centered Design (UCD) methodology was included. UCD methodologies ensure that the design and implementation of the project are always related to the actual user needs. UCD plans and schedules were reported for the main FrailSafe components involving end-user interaction:

- The FrailSafe sensor network and wearable sensing system,
- The personalized information visualization and decision support system,
- The FrailSafe game suite, and
- The integrated FrailSafe system

A number of UCD methods for design and implementation, including questionnaires, focus groups, prototyping and performance measurements will be employed at specific months during the project for each of the above components.

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A. QUESTIONNAIRES

MATERIA GROUP
CARE - NURSING - REHABILITATION

Horizon 2020
European Union funding
for Research & Innovation

European Project Horizon 2020

Advancing active and healthy ageing with ICT: Early risk detection and intervention

1. Please indicate your relation to the project:

☐ Participant in the project

☐ Candidate participant in the project

☐ Healthcare professional (doctor, pharmacist, nurse, psychologist, social worker, sociologist, etc.)

☐ Relative to a participant

2. Have you used any of the project tools?

☐ BELT ☐ AR GLASSES ☐ TABLET ☐ BLOOD PRESSURE MONITOR

☐ DYNAMOMETER ☐ VEST ☐ SMARTPHONE ☐ BEACONS ☐ GAMES

Questions about the project

1. Do you think this project is important?

   ☐ YES ☐NO

2. Are you willing to participate/continue participating in this program?

   ☐ YES ☐NO

Questions about the belts and vests (if you have seen or worn them)

1. Would you be willing to wear a belt or a vest for some hours in your daily life?

   ☐ YES ☐NO

2. Did you find anything difficult to use? If yes, please specify:

…… ……..
……

Questions about the games (if you have used them)

1. Did you like the games?

☐ YES ☐NO

2. Did you find the games easy or hard?

☐ EASY ☐ HARD

3. Did you find the games difficult to use?

☐ YES ☐NO

4. Could you play the games without any assistance from someone?

☐ YES ☐NO

5. Please provide any recommendations/suggestions for improvement:

……
……
……

Questions about the AR glasses (if you have used them)

1. Did you find the glasses difficult to use? If yes, please provide details:

   ……
   ……
   ……
2. While wearing the glasses did you have any loss of balance or felt that you are going to fall?

   ☐ YES ☐NO
3. Do you think that you could use the glasses without any assistance from someone?

   ☐ YES ☐NO

Questions about the tablet (if you have used any)

1. Did you find the tablet difficult to use?

   ☐ YES ☐NO
2. If YES, please provide details:

   ……
   ……
   ……
   ……
3. Do you think that you could use the tablet without any assistance from someone?

   ☐ YES ☐NO

Questions about blood pressure measurement (if you have use the device)

1. Did you have any difficulty while measuring your blood pressure by yourself in your home environment?

   ☐ YES ☐NO

2. If YES, what did you find difficult?

   ……
   ……
   ……..

3. Do you think that you could make a habit of using the blood pressure device in your everyday life?

   ☐ YES ☐NO

Questions about the dynamometer (if you have used it)

1. Did you have any difficulty while using the dynamometer?

   ☐ YES ☐NO

2. If YES, what did you find difficult?

   ……
   ……
   ……..

3. Do you think that you could use the dynamometer without any assistance from someone?

   ☐ YES ☐NO

Questions about the smartphone (if you have used it)

1. Did you have any difficulty while using the smartphone?

   ☐ YES ☐NO

2. If YES, what did you find difficult?

   ……
   ……
   ……..

3. Do you think that you could use the smartphone without any assistance from someone?

   ☐ YES ☐NO