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# Grant Agreement No. 250505

# inCASA

# Integrated Network for Completely Assisted Senior citizen's Autonomy

# D2.2 Requirements Consolidation and Prioritisation Iteration 1

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# **Executive summary**

This document introduces user requirements consolidation and prioritisation for the first phase of the inCASA project, to be part of the piloting activities, introducing the chosen methodologies and presenting the first iteration of requirement consolidation and prioritisation.

The Requirements Gathering process, performed on D2.1 and completed for the first iteration on the D2.2, has the main objective to study the work to be performed and then specifies the solution that could help to perform that work, by analysing stakeholder needs and "wants", by consolidating their requirements and by prioritising them.

As an outcome of this first process, the Requirements Specification provides a complete description of the first phase functionality and behaviour requirements of the solution. After that, system Modelling produces working models of the functions and data needed by the solution, as well as models of the work to support the requirements process iteratively.

Solution Design turns the abstract specification into a design suitable to go out on a real environment. Once developed and integrated, the solution is used, and this real-world experience inevitably provides more new requirements.

Lists of functional, technological and non-functional requirements have been realized and described with contribution from most of the members of the Consortium. Policy, standards and ethical requirements have been introduced as part of the solution development and deployment by the first phase, highlighted as High priority requirements.

This deliverable contains a description of the requirements engineering process, applied to the inCASA project, describing the gathering phase, the validation framework for user requirements and the methodology for prioritisation. It lists also the consolidated requirements with priorities and Functional and Regulatory/Business Risk assessment. It will list also the non functional requirements.

This deliverable also presents the model for service delivery for the TeleCare area, by describing the Habits model with relative specific requirements, the Alerts triggering model and the workflow for taking actions in dependence of the selected scenario of pilot implementation. This model, because of his nature as "core" of the inCASA project, has to be developed independently from the pilot sites implementation, therefore it is presented in a separate chapter with specific requirements (the almost 100% of them are anyway present at a higher level in the use case to be implemented on pilot sites).

Fundación Hospital de Calahorra (FHC) in Spain has, due to various internal problems, not been able to finally define the clinical focus of the pilot and allocate the necessary resources to start the pilot in the first iteration and is therefore not included in the current deliverable. A further discussion of this issue will follow and the proposed solution will be provided in the next Progress Report.

# **1** Introduction

The present Deliverable 2.2 is the first iteration of the deliverableT2.2 of the inCASA project. According to the strategic approach of the project, described in the DoW, this first iteration should introduce the background for many of the other Work Packages. After analysing the collected information coming from the D2.1 it goes on to evaluate the viewpoints of the potential end-users and the stakeholders about their needs and expectations, to be translated into technical system requirements. Therefore it is coherent with the objectives of the WP2, which are "The WP2 work will result in a weighted matrix of requirements that the system has to fulfil. The matrix includes quantitative attributes, such as the number of devices to address, and qualitative factors, e.g. the ease of use, comfort, autonomy, privacy, fear of surveillance, inclusion and techno-animism. The qualitative aspects are, if possible, quantified to ease the system assessment".

When it comes to the design and development of new devices and services for independent living, the specific requirements of users have to be taken into account as well. They must ensure and guarantee an accessibility and usability by older people, people with various disabilities as well as other users. This can also be found within the DoW and can be addressed as: "A user requirement analysis will be based on existing knowledge gained from previous user trials, several research studies, living lab experience of Telefonica, and the results of the SENIOR<sup>1</sup> project on Social ethical and privacy needs in ICT for older people. The existing knowledge will be augmented by the inCASA project undertaking of its own supportive interviews and surveys by guestionnaires. User requirements will be refined aligned with the iterative development approach" (See DoW).

Especially elderly people have particular user requirements, (e.g. due to their restricted ability to hear, to see or to control most ICT equipment). However, it must be borne in mind that elderly people do not build up a homogeneous group. They differ by age, sex, degree of impairment, biography, income, education, religion, culture, etc. Furthermore, the user's awareness, practical experiences, and expectations regarding technology have to be taken into account too, making standardised technological solutions not sufficient. Customised and adapted to the particular needs of elderly people, they might however, enable realistic new business models.

Nevertheless, ethical issues in social and health care particularly affect the elderly for several reasons: older people are sick more often than younger people, they suffer more from being in the end stage of various chronic progressive degenerative diseases and are more likely to lack the capacity to make critical decisions when such decisions have to be made. Therefore, many aspects have to be taken into serious consideration when approaching them.

### 1.1 Purpose and content of this deliverable

Purpose of this deliverable, compliant to the iterative process of inCASA project, is to present the User Requirements for the first phase of project, providing a consolidated list of functional requirements with pilot sites prioritisation and Risk assessment related. In order to achieve this, the present deliverable D2.2 aims at:

- summarizing the input findings emerged from the results of D2.1, for each pilot site; •
- introducing a list of functional and technological requirements to feed technical • workpackages for analysis and system specifications;
- describing the methodology to consolidate and validate the requirements and the Use • Cases:
- introducing the methodology to prioritise the requirements related to the selected Use •

<sup>&</sup>lt;sup>1</sup> Social Ethical and Privacy Needs in ICT for Older People: A DIALOGUE ROADMAP – Project funded under 7th FWP (Seventh Framework Programme) - Research area: ICT-2007.7.1 ICT and ageing - http://seniorproject.eu/ Version 2.5 7

Cases;

- providing a list of consolidated, prioritised ad risk assessed functional and technological requirements for the pre-pilot and for the first phase of inCASA pilots;
- providing a list of non-functional requirements.

### **1.2 Outline of this deliverable**

Chapter 2 describes the requirements engineering process applied to the inCASA project, describing the gathering phase and the validation framework for user requirements.

Chapter 3 describes the process of consolidation of user requirements step by step.

Chapter 4 is dedicated to the methodology for prioritisation. It will list the consolidated requirements with priorities and risk assessment and the outcomes of the prioritisation for the first iteration.

Chapter 5 presents the requirements of monitoring of User Habits and the model of service delivery for the TeleCare area, by describing the habits model with related requirements, the alerts triggering model and the workflow for taking actions. This chapter presents specific requirements, independent from the pilot's needs and "wants" to be developed in their countries.

Chapter 6 lists the non-functional requirements which could affect the first phase of the project.

Chapter 7 summarizes the outcomes of the first iteration of consolidation and prioritisation of user requirements.

# **2** Requirements Engineering Process

The requirement engineering process adopted by inCASA is iterative, thus allowing for a continuous fine-tuning of the requirements which will be documented in the forthcoming and ensuing deliverables D2.4 Requirements consolidation and prioritisation iteration 2 and D2.6 Requirements consolidation and prioritization iteration 3. The functional, technological and non-functional requirements derived will then be integrated and generalised to form a package of user requirements that will be fed into WP 3 - Architecture Design, were the requirements will be more technically described and turned into system specifications.

Requirements engineering is one of the most important steps because an effective elicitation process will provide a set of requirements that can be used by the software development team. Requirement gathering also constitutes the first phase of the user validation process which is crucial to carry out when developing a new service.

User validation is the testing and assessment of a system with the goal to prove that it realises the benefits expected by the stakeholders (i.e. everyone who has an interest in the inCASA platform services and its applications: users and administrators but also the companies which develop the applications and services). Examples can be such as added value of the services, improvement in health and/or social situation for end-users, new methods of collaborative working, etc. In what follows, a description of the validation methodology is given with focus on the first phase: the requirements phase.

The Requirements Gathering process, performed on D2.1 and completed for the first iteration on the D2.2, has the main objective to study the work to be performed and then specifies the solution that could help to perform that work, by analysing stakeholder needs and "wants", by consolidating their requirements and by prioritising them.

As an outcome of this first process, the Requirements Specification provides a complete description of the first phase needed functionality and behaviour of the solution. After that, system Modelling produces working models of the functions and data needed by the solution, as well as models of the work to support the requirements process iteratively Solution Design turns the abstract specification into a design suitable to go out on a real environment.

Once developed and integrated, the solution is used, and this real-world experience inevitably provides more new requirements. Due to the nature of the project, a complete Requirements Specification does not have to be produced before design and construction begin. In fact, a minimal set of requirements components can be used as a guide to planning iterations.

The next figure illustrates the role of requirements in the inCASA project development life cycle:

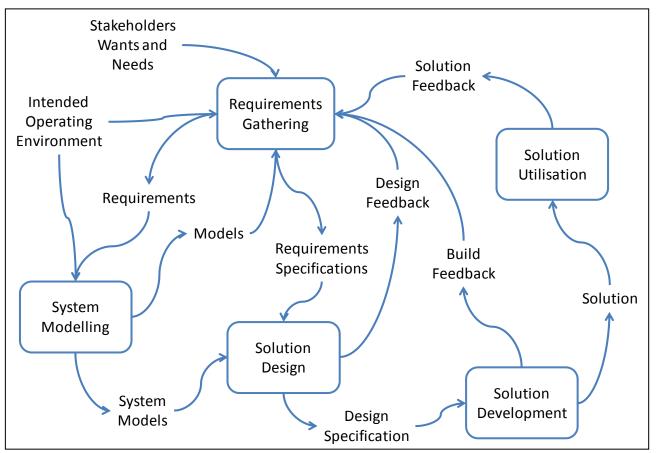


Figure 1 - The inCASA project life-cycle

## 2.1 Purpose of user validation

The purpose of user validation is to assure that the results of the development project - i.e. the implemented result - is in agreement with the needs and requirements of the stakeholders and accepted by these in the end. User validation, including such topics as analysis of user needs, contextual inquiry, ethnographic analysis, usability testing, or user satisfaction measurement, is a mature approach now, based on scientific knowledge, and proven and tested methods [1]. There are a number of sources of information, which help to introduce the approach within development teams and projects. Introductory information, handbook, and extensive information on methods used in user validation are available for instance www.vnet5.org. The site introduces sound and proven procedures and methods which cover all aspects of user validation - although this is by no means the only view of best practice in the field as others offer similar information. Within VNET5, brief descriptions are given for the practitioner who has to plan user validation in a development project, and links to further information.

A question raised frequently is whether the same methods which were developed in the context of office software, transaction processing, or devices such as communication and navigation tools are applicable to high innovative products and services which focus on information and content. Namely, inCASA largely presents the same problems for user validation as any other software development project proposing new innovative services and applications. The innovative challenge may be met by using care in the approach, and awareness of the fact that comparison with existing applications and services, and the use of previous experience may not be possible.

### 2.1.1 User validation framework plan

User validation is the technical implementation of a user-centred development process. The main aim is to assure that the application developed meets the needs and the user requirements and can be recommended for adoption. User validation activities assume different forms in the phases of the lifecycle of a new service:

- In the **requirements phase** the focus is on the analysis of user needs and requirements, and the context in which the new service will be used. In addition, the elicitation of benchmark data from competitive systems may be useful as a baseline for the development of new applications. For the inCASA project, this is the focus of WP2.
- In the design and **implementation phase** the early and efficient detection of shortcomings and flaws in the design is the main aim of the user validation. Methods used can include expert evaluation, cognitive walkthroughs and usability tests of prototypes. Users should be involved as soon as a sufficiently stable and capable prototype is available. For the inCASA project, this is the focus of WP5 Solution Integration and the pre-pilot phase. A self-assessment tool to support the pre-pilot in the assessment of standards and indicators will also be developed in this phase.
- User **performance measurements** are the domain of field trials [2], where controlled conditions are needed to assure that valid and interpretable results are generated. Other methods used should include subjective assessment of system quality by users, and the collection of data, which can serve as performance benchmarks for customers. For the inCASA project, this is the focus of WP6 Pilot Use Cases where the pilot sites will implement, evaluate and validate the services, but also use the self-assessment tool developed during the pre-pilot phase. In addition, WP7 Business Modelling and Employment will produce the validation plan related to the impact regarding the stakeholders (e.g. business plans).

In the present deliverable, we are mainly concerned with the first phase of user validation, i.e. the requirements phase, or more specifically, the gathering, consolidation and prioritisation of user requirements.

### 2.2 Requirements phase

Requirements are descriptions of how the system should behave, application domain information, constraints on the system's operation, or specifications of a system's property or attribute. The requirements are the result of the engineering process that the inCASA project has started. This is a continuous iterative process driven by an adopted user-centred design (UCD) approach and not a stage or phase in the way.

An incomplete requirements analysis tends to lead to problems later in the system development. This is why it is important to use an iterative approach to the entire validation process. As a consequence, the current deliverable D2.2 should be considered as a first initial version of the requirements that will be the basis for updated and changed requirement reports as new requirements arise or outdated ones disappear in the iterations of the project or by the pre-pilot phase.

The requirements can be divided in two<sup>2</sup>:

<sup>&</sup>lt;sup>2</sup> According to Volere – Requirements Specification Template 1995 - 2006 Version 2.5 11

*Functional requirements* are fundamental or essential subject matter of the product. They describe what the product has to do or what processing actions it has to take:

- The scope of the work (changes to an existing manual or automated system)
- The scope of the product
- Functional and data requirements (for the activity of the product).

*Non functional requirements* are the properties that the functions must have, such as performance and usability. These requirements are as important as the functional requirements for the product's success as they also cover:

- Look and feel requirements (intended appearance for end-users)
- Usability and humanity requirements (based on the intended end-users)
- Performance requirements (how fast, big, accurate, safe, reliable...)
- Operational requirements (what is the intended operating environment?)
- Maintainability and portability requirements (how changeable it must be?)
- Security requirements (security, confidentiality and integrity)
- Cultural and political requirements (human factors).
- Legal requirements (Regulatory and Standards)

Application developers have to ensure that their applications are compliant to regulatory constraints or other (industry) standards. The inCASA solution will be designed to be applicable in different application domains which intentionally will include the usage in an international context. Constraints on inCASA applications can therefore be very complex and depend on many factors. Data protection directives, for example, may vary between countries and the system should be able to adapt to the local (legal) requirements. The forthcoming deliverable D2.3 European country policies and ethical package will look closer at national policies, and additional analysis on this issue will also be carried out in WP7 Business Modelling and Deployment.

#### 2.2.1 Analysis of user needs, requirements, and preferences

The requirements and needs of groups of users are analyzed by detailed studies of the application context, based on the involvement of experts for the application domain. In addition to the factors, which are part of a systematic requirements analysis in traditional terms, security needs and sustainable business models are investigated [4].

The needs of users are not fixed in the sense that precise requirements, constraints, and preferences are not maintained under all conditions, but there is a certain amount of "elasticity". One attribute (for example speed of operation) may be traded for another attribute, for example price.

Users who have some experience with a service are quite capable to answer questions, which allow the analysis of the user preferences in terms of tradeoffs. A meaningful (quantitative) analysis demands that a substantial amount of data is available. Otherwise interview and rating techniques may allow the collection of data, which give an indication of the tradeoffs which users consider when selecting services or products for use and purchase.

Given the high cost of conducting studies of tradeoffs, these will be considered towards the end of the project if feasible, and if the expected results justify the effort. This would be the case if it appears desirable to know the value of offering specific functionality and quality to users.

The result would allow estimates of the value of adding specific quality features to the services, and would indicate which main quality features users would like to see integrated into application packages.

Quality will decide the success of the inCASA solution on the market. Quality is a combination of all features and properties of the inCASA solution, which determine its attractiveness and value for the stakeholders.

However, quality means different things to different people. The purpose and the tasks for which the inCASA platform will be used play an important role in defining the preferences for the service features and properties, while subjective factors define the preferences of users for style and aesthetics of the user interface. For example, quality of use is an issue from the viewpoint of end-users whereas service and/or technology provider-users are more concerned about the total cost of ownership of a service.

User requirements analysis should result in a list of features and properties of the inCASA platform including quality criteria, which are considered relevant by the users. User validation carried out later in the project, i.e. during the pre-pilot phase, will test if these quality requirements are fulfilled.

### 2.2.2 Specific demands and challenges in the inCASA project

A frequent argument is that very innovative technology can not be guided by user and market analysis at all, because the users will not be able to answer questions relating to the innovative product before full scale products and the required infrastructure are available in full. This is an argument worth taking into account, but the response should be to adapt the approach to this special challenge, and not to rely on luck entirely. Experience has shown that the likelihood of error is quite large, and hopes for grand successes of new products and large markets are often not fulfilled. It is advisable and necessary to apply user-centred design principles to innovative development projects as well.

inCASA has taken the approach of focusing not only on the user's needs and requirements, but also his/her fears and concern, e.g. fear of falling, fear of isolation, anxiety regarding controlling diabetes etc., as these are often much easier for end-users to name than what their needs are. In the specific context of technology, fear of e.g. loss of privacy clearly indicates that it is a requirement that the system is secure and provides adequate protection of data. Including the end-user's fears and concerns may thus be quite useful for the requirements gathering process.

# **3 Requirements Consolidation**

Requirements usually come from people. Therefore the activity performed by the requirements' analysts has been mostly to talk to stakeholders, trying to understand them, listening with attention to what they said, hearing what they didn't say, and doing the best to catch their need. Parallel, the other step has been to read with attention what they wrote on the project documentation.

### 3.1 1<sup>st</sup> Phase Use Cases

The consolidation of Functional User Requirements started from the D2.1 contribution coming from each pilot site. On the D2.1 each pilot site expressed his visions in relation to the of implementation of the inCASA solution in the first phase of the inCASA project (pre-pilot and first period of pilot implementation), by presenting some basic Use Cases of inCASA services delivery.

The Use Cases are developed in a sequential manner describing a process of actions from which the Pilot Sites User Requirements can later be extracted. The use cases thus describe:

- Title
- Overview
- Social/Clinical purpose
- Procedure
- Analysis
- Data fusion
- Alerts
- Feedback to Users/Patients and relatives
- Personalisation
- Devices

At this point, the next step to extract and consolidate the preliminary requirements was to build a framework of needs and constraints and make a synoptic table of what the project should deploy within each pilot site. Table 1 shows an extraction of the built framework, which is not fully introduced here, to show how the consolidation work put the content of the D2.1 for pilot Use Cases on a synoptic Framework:

| KGHNI     | Title          | Overview:  | Social/Clinical purpose:  | Procedure:  | <u>Analysis</u> :   |
|-----------|----------------|--|---|---|---|
| UC-KGHNII | Bady weight    | to the patient about measuring   | worsening of condition, which needs   | Measure every morning after visit to<br>the toilet. It could be considered to<br>have a reminder send to the patient<br>after the toilet flushes between 7 and<br>10am in the morning.  | Weight measurements are compared<br>over two consecutive days. If there<br>are several measurements per day,<br>the data from approximately the<br>same time in the morning are<br>compared.  |
| UC-KGHNI2 | Blood Pressure | to the patient about measuring<br>his/hers blood pressure, check that<br>the patient has done so, and send the   | that can measure systolic, diastolic<br>and average the blood pressure. It<br>should also be able to measure the<br>heart rate (pulse). With these<br>measurements doctors can estimate<br>the efficacy of the medications and<br>the appropriate dosage. They can<br>also see if patients have armythmias,   | Measurements shall be performed<br>e.g. 3 times a day and the average<br>should be calculated. However, for<br>patients with fibrillations, this<br>procedure is not useful. These<br>patients should make the average<br>over more measurements or discard<br>the first measurement before<br>averages are calculated. The patient<br>may be notified of the need to<br>perform the measurement. | Data should be analysed for<br>correctness (should be within certain<br>limits) before being send on to the<br>backend system where a clinical<br>evaluation shall be performed. This<br>evaluation will be based on filtering<br>the measured value or comparing it<br>to a reference value. |
| UC-KGHNI3 | Pulse Oxymetry | This service will monitor the<br>patient's oxygen saturation and<br>follow its trend. If the patient's<br>condition is deteriorating, the doctor<br>and the patient are alerted. | Pulse oximetry is a non-invasive<br>method allowing the monitoring of<br>the oxygenation of a patient's<br>haemoglobin Coxygen saturation<br>(S <sub>CO</sub> ) measures the porcentage of<br>hemoglobin limiting sites in the<br>bloodstream occupied by oxygen. S <sub>CO</sub> is<br>important to fullow in patients with<br>COPD or heart failure. Trends of the<br>values of S <sub>CO</sub> can predict if the patient<br>is deteriorating. Ductors can then<br>increase the medication or ask the<br>patient to come to the haspital before<br>the situation becomes critical. | Measure the S <sub>02</sub> 3 times daily e.g. in<br>connection with blood pressure<br>measurements.  | Values are pre-conditioned at the<br>point of measurement. Trends of the<br>values of S <sub>02</sub> are derived from stored<br>data.  |
| UC-KGHNI4 | Heart Rate     | This service will measure the<br>patient's heart rate when the patient<br>is measuring blood pressure.   | -   | Collect the pulse data from the blood<br>pressure monitor in connection with<br>blood pressure data transmission.<br>Data should be measured at least 3<br>times a day.   | Normal values are inside the range of<br>50 beats per minute and 100 beats<br>per minute.   |

Table 1 - Extraction from the "First Phase Use Cases" framework Table

The second step was to group the Use Cases, by isolating singular Use Cases (to be performed by one Pilot Site) and grouping common Use Cases (to be performed by two or more Pilot Sites), listing them on another table, referred to each pilot partner.

This led to two main tables:

- Common Use Cases
- Singular Use Cases

The next table shows an extraction of the Common Use Cases Table:

| Use Case       | Title       | Overview:  | Social/Clinical purpose:  | Procedure:  | <u>Analysis</u> :  |
|----------------|-------------|--|---|---|--|
| UC-<br>INSERM3 | Body weight | To measure body weight using a<br>balance directly connected to the<br>inCASA platform.  | To collect complementary accurate<br>data that will improve the early<br>detection of abnormalitics in the<br>patient's health condition.   | Patients body weight will be recorded<br>once a day (early morning) using a<br>balance weight transmitting data<br>directly to the inCASA platform. | Weight measurements are compared<br>over several days.   |
| UC-KGHNI1      | Body weight | This service will provide a reminder<br>to the patient about measuring<br>his/hers body weight, check that the<br>patient has done so, and send the<br>measured value to a backend system<br>where it is evaluated and stored. | An increase weight i.e. 1 kilo per day<br>over maximum 2 days is an<br>indication of body fluid retention i.e.<br>worsening of condition, which needs<br>proper intervention of a doctor.                                       | the toilet. It could be considered to<br>have a reminder send to the patient<br>after the toilet finshes between 7 and<br>10am in the morning.      | Weight measurements are compared<br>over two consecutive days. If there<br>are several measurements per day,<br>the data from approximately the<br>same time in the morning are<br>compared. |
| UC-CHC2        | Weight      | Patients who have a diagnosis of<br>CHF and or those whose co-<br>morbidities may suggest weight is an<br>important factor will be provided<br>with a weight scale   | For those patients with CHF, the<br>clinical teams will look to ensure<br>there is no significant change in their<br>weight which may suggest that they<br>are retaining fluid (a sign of<br>deterioration in their condition). | day – preferably by 11am. This will   | The data will then be analysed using<br>the management system to track the<br>patients weight  |

 Table 2 - Extraction from the "Common Use Cases" Table

This preparatory work led to have common and singular descriptions which can then be used to consolidate requirements for the inCASA project first phase.

## 3.2 2<sup>nd</sup> Phase Use Cases

At the moment it is not possible to clearly define how the pilots will develop and as such these use cases will need readjustments/modification in the second phase which is why we have adopted an iterative approach to the requirements prioritisation and consolidation process. Most of the objectives described in Table 3 should be regarded as an actual pilots' wish list, which will eventually be influenced by the first phase's outcomes, indicators and results. This would be the most important driver to address the extension of the pilots in one direction or another, also with the impact of the market progress and business drivers which can change while the first phase is "on the run".

| Pilot | Description   |
|-------|---|
| KGHNI | The second phase of the pilot will expand into longer term, multi-parametric monitoring of physiological and behavioural parameters. It will build on the results of the first pilot phase and will define a new group of older patients, who are living alone and do not have relatives in close vicinity. The expanded use cases for the second phase of the pilot will be described at the end of phase one. However, some elements are already foreseen at present. |

| Pilot  | Description  |
|--------|--|
|        | <i>Local evaluation and data fusion</i><br>It will be desirable to relate one measurement to another, e.g. movement and oximetry. The purpose is to see if there is a correlation between the two. It will be desirable to relate one measurement to another, e.g. movement and oximetry. The purpose is to see if there is a correlation between the two. It will be desirable to relate one measurement to another, e.g. movement and oximetry. The purpose is to see if there is a correlation between the two. It will be desirable to relate one measurement to another, e.g. movement and oximetry. The purpose is to see if there is a correlation between the two. It will also be interesting to combine more parameters such as lower mobility, decreased blood pressure, etc. which could points to a worsening condition, and involve home nurses or social care workers to visit the patient and provide advice and local care. |
|        | <i>Social and healthcare integration - Influence of other parameters</i><br>Depression monitoring, need for medication and rehabilitation also leads to more involvement<br>of home nurses or social care workers.   |
|        | <i>Compliance to medical therapy</i><br>The compliance with prescribed medicine intake is extremely important and one of the most common source of poor medical therapy. An electronic medication dispenser is available which can be used to monitor medicine compliance and alert patients, relatives and healthcare professionals of actual compliance.   |
| INSERM | The second phase of the pilot will expand into long term multi-parametric monitoring of physical and behavioural parameters. It will build on the results of the first pilot phase and will define a new group of older patients. The expanded use cases for this second phase will be described at the end of the first phase of the pilot. However we can already foresee some elements that are relevant to be integrate in the second phase of the pilot. Indeed, the duration of the home recording of the same variables will be prolonged (> 12 weeks for example). Other relevant physiological or behavioural variables can be integrated pending upon patient conditions (blood pressure, oximetry,, and correlation between all the variables). Enrolment of patients older than 75 years, and also complement the existing variables measured.   |
| СНС    | The second phase of the pilot will bring together in a cohesive manner the habits monitoring<br>and clinical monitoring data so that it can be analysed to identify any patterns in the data.<br>Intelligent algorithms will be developed to determine if there is any correlation between<br>change in habits behaviour and deterioration in health.  |
| ATC    | During the second phase, a pilot with around 25-30 users will be set up. The follow up of the project involves the implementation of an integrated system on a wider territorial scale to provide remote monitoring and support for a larger number of older and frail people living in social housing. This with a view to promote prevention, cost savings and integration of response to frail people needs. The aim is to increase the autonomy and independence of elderly people and improve the quality of their life. The goal is to contribute to the reduction of welfare costs through IT integrated systems and research and the networking between the ATC Call Centre and the Local Social Services (social workers, Volunteers, Health Care system).  |
|        | Table 3 – Second Phase Use Cases   |

#### Table 3 – Second Phase Use Cases

The next sections describe the actual consolidation phase.

# 3.3 Consolidation Step One

The approach taken to consolidate the requirements has been to extract single requirements among Common and Singular Use Cases that have been identified on the preparatory phase and inserting them on a specific table.

The work has been proceeding with a first consolidation of descriptions, in order to homogenise the requirements to be coded.

For similar statements singular, shared requirements have been identified and associated to, coding them one by one. See "Code (output)" column.

The result of this "Step One" consolidation is shown on Table 4:

| Use Case<br>(Input) | Description   | Pilot  | Common Description  | Name                                      | Code<br>(Output) |
|---------------------|---|--------|---|---|------------------|
| UC-INSERM3          | 10 balances directly connected to the inCASA platform.  | INSERM | The user should be provided with a  |   |                  |
| UC-KGHNI1           | For example A&D UC-321-PBT Electronic Scale. Bluetooth interface to gateway.  | KGHNI  | Bluetooth Weight Scale measuring  | Weight<br>Scale                           | R01              |
| UC-CHC2             | A weight scale (should record the measurements in KG)   | CHC    | iii Kg  |   |                  |
| UC-KGHNI1           | It could be considered to have a reminder send to the patient   | KGHNI  | The system could send a reminder<br>(sms or tablet alert) to the user to<br>take measurement  | Weight<br>measurem<br>ent<br>Reminder     | R02              |
| UC-INSERM3          | Patients body weight will be recorded once a day (early morning)  | INSERM | The success should allow  |   |                  |
| UC-KGHNI1           | Measure every morning after visit to the toilet.  | KGHNI  | The system should allow   | European and                              |                  |
| UC-KGHNI1           | It is a requirement that the service can be personalised to each<br>individual patient in terms of time of day and increment of the<br>weight measurements.   | KGHNI  | professional users to set the usual<br>timing of measurement (from<br>hh:mm to hh:mm) and the number  | Frequency<br>and<br>Timing of             | R03 R04          |
| UC-CHC2             | Patient to take one measurement per day – preferably by 11am.   | CHC    | of measurements per day and<br>should accept extemporary  | weight<br>measurem                        |                  |
| UC-CHC2             | Where necessary we may request the patient to repeat the measurement in a day or they may choose to send a second reading at another point during the day.  | СНС    | measurements provided by the patient  | ents                                      |                  |
| UC-INSERM3          | Weight measurements are compared over several days.   | INSERM |   |   |                  |
| UC-KGHNI1           | Weight measurements are compared over two consecutive days.   | KGHNI  | The system should allow   | Weight                                    |                  |
| UC-KGHNI1           | If there are several measurements per day, the data from approximately the same time in the morning are compared.   | KGHNI  | measurement data visualization<br>and extraction organized per  | measurem<br>ents                          | R05              |
| UC-CHC2             | The data will then be analysed using the management system to track the patients weight   | СНС    | day/per week/per month  | Analysis                                  |                  |
| UC-INSERM3          | All the data should be store in a dedicated computer with permanent internet connection to the inCASA server.   | INSERM | All data should be stored on the<br>inCASA Repository through a<br>permanent internet connection  | Weight<br>measurem<br>ent Data<br>Storage | R06              |
| UC-INSERM3          | If there is a consistent decrease in body weight between several data points, the nurse is alerted  | INSERM | The system should send an alert<br>(On Screen Alert/SMS) to the   |   |                  |
| UC-KGHNI1           | If the is a consistent increase in body weight of more than 1 kg between three data points, the responsible doctor is alerted.  | KGHNI  | operator (Nurse/Clinician/Case<br>Manager) if there is a consistent   |   |                  |
| UC-CHC2             | The clinician will be alert when there is a variance away from the desired or expected  | СНС    | absolute or across time. The  | Alerts for<br>Weight                      | R07              |
| UC-CHC2             | The system should allow for clinicians to enter personalised optimum target values for each patient as well as be able to enter levels of change in weight over a defined time scale e.g. >1.4kg over 3 days. | СНС    | system should allow professional<br>users to set rules: the number of<br>measurements to compare; the<br>limit of the variation (if more than<br>XX UOM (UNIT OF MEASURE) |   |                  |

| Use Case<br>(Input) | Description  | Pilot | Common Description   | Name                                    | Code<br>(Output) |
|---------------------|--|-------|--|---|------------------|
|                     |  |       | across X continuous<br>measurements/over XX days) to<br>send the alert   |   |                  |
| UC-KGHNI3           | Several pulse oximetry devices exist in the Continua alliance list.  | KGHNI | The user should be provided with a   | Pulse                                   | R08              |
| UC-CHC3             | A pulse oximeter   | CHC   | wireless pulse oximeter  | Oximeter                                | 100              |
| UC-KGHNI3           | Measure the SO2 3 times daily e.g. in connection with blood pressure measurements.   | KGHNI | The system should allow professional users to set the usual  | Frequency                               |                  |
| UC-CHC3             | We will ask each patient to take one measurement per day – preferably by 11am.   | CHC   | timing of measurement (from<br>hh:mm to hh:mm) and the number  | and<br>Timing of                        | R03 R04          |
| UC-CHC3             | Where necessary we may request the patient to repeat the measurement in a day or they may choose to send a second reading at another point during the day.                               | CHC   | of measurements per day and<br>should accept extemporary<br>measurements provided by the<br>patient  | SpO2<br>measurem<br>ents                |                  |
| UC-KGHNI3           | Values are pre-conditioned at the point of measurement. Trends of the values of SO2 are derived from stored data.  | KGHNI | The system should allow measurement data visualization   | SpO2<br>measurem                        | R05              |
| UC-CHC3             | The data will be analysed using the management system to track the patients' SpO2  | CHC   | and extraction organized per day/per week/per month  | ents<br>Analysis                        | RUS              |
| UC-KGHNI3           | All data should be stored in a suitable Electronic Healthcare Record.  | KGHNI | All data should be stored on the<br>inCASA Repository through a<br>permanent internet connection   | SpO2<br>measurem<br>ent Data<br>Storage | R06              |
| UC-KGHNI3           | Doctors are alerted of deteriorating condition   | KGHNI | The system should send an alert  |   |                  |
| UC-CHC3             | The clinician will be alerted when there is a variance away from the desired or expected   | CHC   | (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case  |   |                  |
| UC-CHC3             | The system should allow for clinicians to enter personalised<br>optimum target values for each patient as well as be able to enter<br>levels of change in Spo2 over a defined time scale | СНС   | Manager) if there is a consistent<br>variation on the measurements,<br>absolute or across time. The<br>system should allow professional<br>users to set rules: the range of<br>normality and the limit of the<br>variation to send the alert | Alerts for<br>SpO2                      | R07              |
| UC-KGHNI3           | Confirmation of changes of medication shown on display and send via SMS to relatives.  | KGHNI | The system could allow professional users to plan for single coded   |   |                  |
| UC-KGHNI3           | Call for visits to the outpatient clinic can be confirmed by SMS to the patient and relatives  | KGHNI | activities (e.g. medication change,<br>appointment) and then send an<br>SMS to patient and/or<br>Relatives/caregivers  | SpO2 SMS                                | R10<br>R11       |
| UC-KGHNI2           | For example A&D UA767-PBT Blood Pressure Monitor with two sizes of inflatable arm cuffs. Bluetooth interface to gateway. One device for each of the 5 patients in a group.               | KGHNI | The user should be provided with a<br>Bluetooth blood pressure Monitor<br>measuring in mmHg with pulse   | Blood<br>Pressure<br>Monitor            | R12              |
| Version 2.5         | 20   | 2     | 28-02-2011   |   |                  |

| Description Pilot Common Description  |   | Name   | Code<br>(Output)  |   |
|---|---|--|---|---|
| Blood Pressure monitor that will record systolic, diastolic (mmHg) and pulse.   | CHC   | metering capabilities  |   |   |
| Measurements shall be performed e.g. 3 times a day.   | KGHNI   | The system should allow  | _   |   |
| Collect the pulse data from the blood pressure monitor in connection with blood pressure data transmission.   | KGHNI   | professional users to set the usual timing of measurement (from  | and   |   |
| Patient will take one resting blood pressure measurement per day – preferably by 11am.  | CHC   | hh:mm to hh:mm) and the number<br>of measurements per day and<br>should accept extemporary<br>measurements provided by the<br>patient  | Blood   | R03<br>R04  |
| Where necessary we may request the patient to repeat the measurement in a day or they may choose to send a second reading at another point during the day.  | CHC   |  | measurem<br>ents  |   |
| The average should be calculated  | KGHNI   |  |   |   |
| However, for patients with fibrillations, this procedure is not useful.<br>These patients should make the average over more measurements<br>or discard the first measurement before averages are calculated.  | KGHNI   | professional users to set the<br>number of measurements to<br>compare and the formula (e.g.<br>average) to be applied to the<br>selected measurements  | Blood<br>Pressure<br>Monitoring<br>calculation  | R13   |
| The patient may be notified of the need to perform the measurement.   | KGHNI   | The system could send a reminder<br>(sms or tablet alert) to the user to<br>take measurement   | Blood<br>Pressure<br>measurem<br>ent<br>Reminder  | R02   |
| Data should be analysed for correctness (should be within certain<br>limits) before being sent on to the backend system where a clinical<br>evaluation shall be performed. This evaluation will be based on<br>filtering the measured value or comparing it to a reference value. | KGHNI   | The system should allow<br>measurement data visualization  | Blood   | R05   |
| The clinical teams will look to ensure a patients' Blood Pressure is within pre-defined limits e.g. 140/85.   | CHC   | and extraction organized per day/per week/per month  | Analysis  | RUS   |
| The data will then be analysed using the management system to track the patients current blood pressure measure.  | CHC   |  |   |   |
| All data should be stored in a suitable Electronic Healthcare Record.   | KGHNI   | All data should be stored on the<br>inCASA Repository through a<br>permanent internet connection   | Blood<br>Pressure<br>Data<br>Storage  | R06   |
| If values are outside certain bands, the responsible doctor should be alerted.  | KGHNI   | The system should send an alert<br>(On Screen Alert/SMS) to the  |   |   |
| The clinician will be alerted when there is a variance away from the desired or expected  | СНС   | operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the measurements,<br>absolute or across time. The<br>system should allow professional  | Alerts for<br>Blood<br>Pressure   | R07   |
|   | Blood Pressure monitor that will record systolic, diastolic (mmHg)<br>and pulse.<br>Measurements shall be performed e.g. 3 times a day.<br>Collect the pulse data from the blood pressure monitor in<br>connection with blood pressure data transmission.<br>Patient will take one resting blood pressure measurement per day<br>– preferably by 11am.<br>Where necessary we may request the patient to repeat the<br>measurement in a day or they may choose to send a second<br>reading at another point during the day.<br>The average should be calculated<br>However, for patients with fibrillations, this procedure is not useful.<br>These patients should make the average over more measurements<br>or discard the first measurement before averages are calculated.<br>The patient may be notified of the need to perform the<br>measurement.<br>Data should be analysed for correctness (should be within certain<br>limits) before being sent on to the backend system where a clinical<br>evaluation shall be performed. This evaluation will be based on<br>filtering the measured value or comparing it to a reference value.<br>The clinical teams will look to ensure a patients' Blood Pressure is<br>within pre-defined limits e.g. 140/85.<br>The data will then be analysed using the management system to<br>track the patients current blood pressure measure.<br>All data should be stored in a suitable Electronic Healthcare<br>Record.<br>If values are outside certain bands, the responsible doctor should<br>be alerted. | Blood Pressure monitor that will record systolic, diastolic (mmHg)<br>and pulse.CHCMeasurements shall be performed e.g. 3 times a day.KGHNICollect the pulse data from the blood pressure monitor in<br>connection with blood pressure data transmission.KGHNIPatient will take one resting blood pressure measurement per day<br>- preferably by 11am.CHCWhere necessary we may request the patient to repeat the<br>measurement in a day or they may choose to send a second<br>reading at another point during the day.CHCThe average should be calculatedKGHNIHowever, for patients with fibrillations, this procedure is not useful.<br>These patients should make the average over more measurements<br>or discard the first measurement before averages are calculated.KGHNIData should be analysed for correctness (should be within certain<br>limits) before being sent on to the backend system where a clinical<br>evaluation shall be performed. This evaluation will be based on<br>filtering the measured value or comparing it to a reference value.CHCThe data will then be analysed using the management system to<br>track the patients current blood pressure measure.CHCAll data should be stored in a suitable Electronic Healthcare<br>Record.KGHNIIf values are outside certain bands, the responsible doctor should<br>be alerted.KGHNI | Blood Pressure monitor that will record systolic, diastolic (mmHg)<br>and pulse.         CHC         metering capabilities           Measurements shall be performed e.g. 3 times a day.         KGHNI         The system should allow<br>professional users to set the usual<br>timing of measurement (from<br>Patient will take one resting blood pressure measurement per day<br>- preferably by 11am.         The system should allow<br>professional users to set the usual<br>timing of measurements for day and<br>should accept extemporary<br>measurements in a day or they may choose to send a second<br>reading at another point during the day.         CHC         The system should allow<br>professional users to set the usual<br>timing of measurements per day and<br>should accept extemporary<br>measurements provided by the<br>patient           The average should be calculated         KGHNI         The system should allow<br>professional users to set the<br>number of measurements to<br>compare and the formula (e.g.<br>average) to be applied to the<br>selected measurements           The patient may be notified of the need to perform the<br>measurement.         KGHNI         The system could send a reminder<br>(sms or tablet alert) to the user to<br>take measurement           Data should be analysed for correctness (should be within certain<br>limits) before being sent on to the backend system where a clinical<br>within pre-defined limits e.g. 140/85.         KGHNI         The system should allow<br>measurement data visualization<br>and extraction organized per<br>day/per week/per month           All data should be stored in a suitable Electronic Healthcare<br>Record.         CHC         All data should be stored on the<br>inCASA Repository through a<br>permanent internet connection           If values are outsid | Blood Pressure monitor that will record systolic, diastolic (mmHg)<br>and pulse.         CHC         metering capabilities           Measurements shall be performed e.g. 3 times a day.         KGHNI         The system should allow<br>professional users to set the usual<br>timing of measurement (from<br>hh:mm to hh:mm) and the number<br>of measurements provided by the<br>patient will take one resting blood pressure measurement per day<br>where necessary we may request the patient to repeat the<br>measurement in a day or they may choose to send a second<br>reading at another point during the day.         CHC         Frequency<br>measurements provided by the<br>patient           The average should be calculated         KGHNI         The system should allow<br>professional users to set the<br>patient         Blood           However, for patients with fibrillations, this procedure is not useful.<br>The patient may be notified of the need to perform the<br>measurement.         KGHNI         The system could send a reminder<br>(sm or tablet alert) to the user to<br>take measurement         Blood<br>Pressure<br>(sm or tablet alert) to the user to<br>take measurement         Blood<br>Pressure<br>measurement           Data should be analysed for correctness (should be within certain<br>limits) before being sent on to the backend system where a clinical<br>evaluation shall be performed. This evaluation will be based on<br>filtering the endined insci e.g. 140/85.         Blood<br>Pressure<br>ad extraction organized per<br>day/per week/per month           All data should be stored in a suitable Electronic Healthcare<br>Record.         KGHNI         All data should be stored on the<br>inCASA Repository through a<br>permant internet connection         Blood<br>Pressure<br>Manalysis           The d |

| Use Case<br>(Input) | Description  | Pilot  | Common Description  | Name   | Code<br>(Output) |
|---------------------|--|--------|---|--|------------------|
|                     |  |        | users to set rules: the range of<br>normality and the limit of the<br>variation to send the alert   |  |                  |
| UC-INSERM2          | 10 pad interfaces directly connected to the inCASA platform.   | INSERM | The user should be provided with a Wireless Tablet connected to the inCASA platform   | Symptoms<br>self<br>assessmen<br>t device            | R14              |
| UC-INSERM2          | Patients will self-assess their symptoms on a pad interface connected to the inCASA platform once a day (in the evening).  | INSERM | The system should allow<br>professional users to set the usual<br>timing of assessment (from hh:mm<br>to hh:mm) and should accept<br>extemporary self assessment<br>provided by the patient   | Frequency<br>and timing<br>of Self<br>assessmen<br>t | R03<br>R04       |
| UC-INSERM2          | Symptoms will include pain, fatigue, nausea, disturbed sleep, distress, drowsiness, nausea, anorexia, and vomiting.  | INSERM | The system should allow the   | Self   |                  |
| UC-CHC5             | The monitoring gateway will act as a data collection source direct<br>from the patient. For example the hub should prompt and instruct<br>the patient in the use of the devices, provide visual / audio<br>feedback of the measurement, display disease specific questions<br>and allow the patient to input the answer to those questions | СНС    | professional users to introduce<br>specific questions or questionnaires<br>to be administered to the patient<br>and assign value to each answer<br>and then calculate scores  | Assessme<br>nt<br>questionna<br>ire                  | R15              |
| UC-INSERM2          | If the self-assessed symptoms scores are worsening, an alarm will<br>be generated  | INSERM | The system should send an alert<br>(On Screen Alert/SMS) to the<br>operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the score of<br>assessment, absolute or across<br>time. The system should allow<br>professional users to set rules<br>about the limit of the variation (if<br>more than XX UOM (UNIT OF<br>MEASURE) across X continuous<br>measurements/over XX days) to<br>send the alert | Self<br>Assessme<br>nt Alerts                        | R07              |
| UC-KGHNI8           | Wireless movement sensors are inexpensive and easy to install.   | KGHNI  | The user's house should be  |  |                  |
| UC-CHC4             | PIR motion detector. In addition the time and duration of each event will be recorded.   | СНС    | provided by battery operated<br>wireless sensors to detect  | Indoor<br>movement                                   | R16              |
| UC-ATC2             | contact/movement sensors   |        | movement of the user inside the<br>house, recording time and duration<br>of detected movement events  |  |                  |

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| Use Case<br>(Input) | Description   | Pilot  | Common Description   | Name                                  | Code<br>(Output) |  |
|---------------------|---|--|--|---------------------------------------|------------------|--|
| UC-KGHNI8           | All data should be stored in a suitable Electronic Healthcare Record.   | KGHNI  | All data should be stored on the inCASA Repository through a   | Indoor<br>movement                    | R06              |  |
| UC-ATC2             | the data will be sent and processed   | ATC  | permanent internet connection  | data<br>storage                       |                  |  |
| UC-KGHNI8           | Movements are continuously measured in different sections of the home.  | KGHNI  | Movement inside the house is   | Frequency<br>and                      |                  |  |
| UC-ATC2             | The service will monitor the indoor movements of the user, in order to identify gaps and anomalies and to send alerts   | ATC  | continuously monitored by the<br>system  | Timing of<br>indoor                   | R03              |  |
| UC-CHC4             | A PIR motion detector will also be placed in a location e.g. hall where foot traffic is the greatest.   | CHC  | system   | Movement<br>monitoring                |                  |  |
| UC-KGHNI8           | CHF patients have in general reduced mobility. Another<br>explanation for this reduced mobility could be the onset of<br>depression something very common in these patients. The<br>movement sensors will play a key role in the "social part" of the<br>project as they can help us produce conclusions of the patient's<br>psychological status much easier than any other clinical monitoring<br>device. | KGHNI  |  |                                       |                  |  |
| UC-CHC4             | A change / reduction in a person's movements can be indicative of deterioration and the clinicians would like to understand how and if this change can be seen prior to any changes to physiological measurements.  | ioration and the clinicians would like to understand how and if change can be seen prior to any changes to physiological CHC changes from a "Normal Habits", |  | Movement<br>Monitoring                | R17              |  |
| UC-ATC2             | The service will monitor the indoor movements of the user, in order to identify gaps and anomalies and to send alerts   | ATC  | profile across 2 weeks of monitoring   | Analysis                              |                  |  |
| UC-CHC4             | It is expected that we will be able to build up a model of "average" activity within a person's home. This model of a person's activity may take up to one or two weeks to create.  | СНС  |  |                                       |                  |  |
| UC-ATC2             | User is not moving for several hours (> 50% of usual movement),<br>or is moving inside his home abnormally, or is moving during the<br>night when she/he usually sleeps, etc: the corresponding signals<br>will be processed and send to verify the level of warning  | g for several hours (> 50% of usual movement),<br>his home abnormally, or is moving during the<br>usually sleeps, etc: the corresponding signals             |  |                                       |                  |  |
| UC-KGHNI8           | The NYHA system relates symptoms to everyday activities and the<br>patient's quality of life. An advanced algorithm needs to be<br>developed that allows the service to distinguish between class II<br>and class III/IV. This algorithm should take into account the<br>movements, the number of people in the home as well as<br>subjective input from the patient.                                       | KGHNI  | The system should correlate<br>movements to an algorithm made<br>to evaluate NYHA class of everyday<br>activities, by taking into account<br>the movements, the number of<br>people in the home as well as<br>subjective input from the patient. | Movement<br>Monitoring<br>calculation | R18              |  |
| UC-KGHNI8           | Healthcare professionals are alerted if the algorithm detects class The system should send an   |  |  | Movement<br>Alerts                    | R07              |  |
| Version 2.5         | 23  | 2  | 28-02-2011   |                                       |                  |  |

| Use Case<br>(Input) | Description  | Pilot | Common Description  | Name                            | Code<br>(Output) |
|---------------------|--|-------|---|---------------------------------|------------------|
| UC-KGHNI8           | There should be a discrimination between patients that already had kinetic problems and the others that did not have. The system should not generate false alarms for the patients of the first category.        | KGHNI | Manager) if there is a consistent<br>variation on the measurement,<br>absolute or across time. The<br>system should allow professional  |                                 |                  |
| UC-ATC2             | A message (SMS/e-Mail/UI Alert) to the operator will be sent if data are out of normal habits  | ATC   | users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alert                                 |                                 |                  |
| UC-CHC4             | The devices will be battery operated pressure pads and will record each time a person sits / lies down and when a person stands / gets out of bed.   | СНС   | The user's house should be<br>provided by battery operated<br>wireless sensors to detect presence   | Bed                             | D10              |
| UC-KGHNI8           | Steinbeis can provide bed sensors that measure the time the patient spends in bed.   | KGHNI | of the user on the bed, recording time and duration of bed  | Permanen<br>ce sensors          | R19              |
| UC-ATC3             | Bed contact/movement sensors   | ATC   | permanence events   |                                 |                  |
| UC-CHC4             | All of the patients within the monitoring program will be provided<br>with a set of habits monitoring sensors. We will then be able to<br>track changes to the average trend e.g. time spent sitting,            | СНС   | The user's house should be<br>provided by battery operated<br>wireless sensors to detect presence<br>of the user on a chair, recording<br>time and duration of bed<br>permanence events                 | Chair<br>Permanen<br>ce sensors | R20              |
| UC-KGHNI8           | All data should be stored in a suitable Electronic Healthcare Record   | KGHNI | All data should be stored on the  | Bed                             |                  |
| UC-ATC3             | the data will be sent and processed  | ATC   | inCASA Repository through a permanent internet connection   | Permanen<br>ce data<br>storage  | R06              |
| UC-ATC3             | The system will process some inputs like: User goes to bed; User stays on bed; User wakes up from bed; User doesn't go to bed.<br>These different patterns will be processed in order to generate alert messages | ATC   | The system should allow<br>professional users to evaluate   | Bed                             |                  |
| UC-CHC4             | The devices will be battery operated pressure pads and will record each time a person sits / lies down and when a person stands / gets out of bed.   | СНС   | changes from a "Normal Habits",<br>by building a "normal habits"<br>profile across 2 weeks of<br>monitoring   | Permanen<br>ce<br>Analysis      | R17              |
| UC-KGHNI8           | A reduction in the average daily mobility (i.e. staying more hours<br>in the bed) is a strong indicator of clinical status worsening.  | KGHNI |   |                                 |                  |
| UC-ATC3             | A message (SMS/e-Mail/UI Alert) to the operator will be sent if data are out of normal habit   | ATC   | The system should send an alert<br>(On Screen Alert/SMS) to the<br>operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the measurement,<br>absolute or across time. The | Bed<br>Permanen<br>ce Alerts    | R07              |

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| Use Case<br>(Input) | Description  | Pilot | Common Description  | Name  | Code<br>(Output) |
|---------------------|--|-------|---|---|------------------|
|                     |  |       | system should allow professional<br>users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alert   |   |                  |
| UC-KGHNI5           | ECGLink is a smartphone application developed by Care2wear (Den mark) which has a 5-point mobile solution. The ECG signals are sent to a central telemetry system via a GSM telephone.   | KGHNI | The user should be provided with a wireless heart rhythm Monitor with at least 3 electrodes measuring rhythm with a basic EKG as output   | Heart<br>Rhythm<br>monitor                                  | R33              |
| UC-KGHNI5           | Recordings can be either continuously or in regular time slots of at least 30 seconds each.  | KGHNI | Data should be transmitted<br>continuously to the inCASA<br>platform or at least in 30" slots<br>regularly  | Frequency<br>and timing<br>of heart<br>rhythm<br>monitoring | R21              |
| UC-KGHNI5           | All ECG data should be registered in the existing telemetry system at the Cardiology Department of the KHGNI   | KGHNI | Data should be stored on the standard cardiological repository of   | Heart<br>Rhythm   | R22              |
| UC-KGHNI5           | ECG signals are analysed for arrhythmia and sinus rhythm. This is best done in an existing telemetry system.   | KGHNI | the KGHNI through integration with the inCASA platform  | data<br>storage   | 1/22             |
| UC-KGHNI5           | If heart rhythm has not returned to sinus rhythm within a set time, the resident doctor is alerted.  | KGHNI | The system should send an alert<br>(On Screen Alert/SMS) to the   |   |                  |
| UC-KGHNI5           | The analysis of the results should take into consideration if the patient has atrial fibrillation and/or other arrhythmias in order not to generate false alarms because it is quite common in such kind of patients to have heart rhythm abnormalities. | KGHNI | operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the measurement,<br>absolute or across time. The<br>system should allow professional<br>users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alert | Heart<br>Rhythm<br>Alert                                    | R07              |
| UC-KGHNI6           | Roche AccuCheck BG devices can be used.  | KGHNI | The user should be provided with a  | Glucose   |                  |
| UC-KGHNI6           | Blood glucose levels are measured in a blood sample using traditional stick methods.   | KGHNI | glucose monitoring device   | Monitoring<br>Device  | R23              |
| UC-KGHNI6           | Diabetic patients measure their blood glucose levels<br>1 or 2 times per day. Non-diabetic patients do it once per week.   | KGHNI | The system should allow<br>professional users to set the usual<br>timing of measurement (from<br>hh:mm to hh:mm) and the number<br>of measurements per day/week<br>and should accept extemporary  | Frequency<br>and timing<br>of glucose<br>monitoring         | R03<br>R04       |
| Version 2.5         | 25   | 2     | 28-02-2011  | 1   |                  |

| Use Case<br>(Input)    | Description Pilot Co   |       | Common Description   | Name  | Code<br>(Output) |
|------------------------|--|-------|--|---|------------------|
|                        |  |       | measurements provided by the patient   |   |                  |
| UC-KGHNI6              | all data should be stored in a suitable Electronic Healthcare Record.  | KGHNI | All data should be stored on the<br>inCASA Repository through a<br>permanent internet connection   | Glucose<br>monitoring<br>data<br>storage              | R06              |
| UC-KGHNI6<br>UC-KGHNI6 | In case of patients that suffer from diabetes mellitus an alert<br>should be generated when blood glucose exceeds 200 mg/dl while<br>in other patients an alert should be generated when blood glucose<br>exceeds 120 mg/dl. | KGHNI | The system should send an alert<br>(On Screen Alert/SMS) to the<br>operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the measurement,<br>absolute or across time. The<br>system should allow professional<br>users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alert | Glucose<br>Monitoring<br>Alerts                       | R07              |
| UC-KGHNI7              | Home INR devices exist but are quite expensive. So there are sticks to be used.  | KGHNI | The user should be provided with a<br>INR monitoring device or provided<br>with a UI to insert manually<br>measurements done with sticks   | INR<br>monitoring<br>device                           | R24              |
| UC-KGHNI7              | INR measurements are performed once per week.  | KGHNI | The system should allow<br>professional users to set the usual<br>timing of measurement (from<br>hh:mm to hh:mm) and the number<br>of measurements per day/week<br>and should accept extemporary<br>measurements provided by the<br>patient  | Frequency<br>and timing<br>of INR<br>Measurem<br>ents | R03<br>R04       |
| UC-KGHNI7              | All INR data should be stored in a suitable Electronic Healthcare Record.  | KGHNI | All data should be stored on the<br>inCASA Repository through a<br>permanent internet connection   | INR<br>measurem<br>ent data<br>storage                | R06              |
| UC-KGHNI7              | The normal range is 1 - 2, but for CHF patients it is better to aim<br>for 2 - 2 5. If the value is greater than 5 the patient is in a risky   |       | INR<br>Measurem<br>ents Alerts   | R07   |                  |

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| 10 Bluetooth wrist actigraph, 10 hubs connected between the<br>Bluetooth actigraph and the inCASA platform for the transmission   |  | system should allow professional<br>users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to cond the plot   |   |   |
|---|--|--|---|---|
|   |  | days) to send the alert  |   |   |
| of the actigraphic data.  | INSERM   | The user should be provided with<br>Bluetooth actigraphs recording   | Actigraphy  | R25   |
| Data will be recorded continuously at the frequency of 1 per minute.  | INSERM   | movement at a frequency of one signal per minute   | Device  |   |
| The actigraph will transmit the recorded data by transmission to the inCASA platform twice a day (early morning and late evening).  | INSERM   | Data should be transmitted to the<br>inCASA platform at least twice a<br>day. This frequency should be<br>customizable during the project.   | Actigraphy<br>Data<br>Transmissi<br>on  | R32   |
| The rest-activity rhythm data are analysed daily through the I <o 3="" along="" assessed="" changes="" daily="" in="" index.="" is="" more.<="" or="" over="" parameter="" process="" recording="" td="" the="" this="" weeks=""><td>INSERM</td><td>The system should allow<br/>professional users to set the usual<br/>timing of measurement (from<br/>hh:mm to hh:mm) and the number<br/>of measurements per day</td><td>Frequency<br/>and timing<br/>of<br/>Actigraphy</td><td>R03</td></o>                              | INSERM   | The system should allow<br>professional users to set the usual<br>timing of measurement (from<br>hh:mm to hh:mm) and the number<br>of measurements per day   | Frequency<br>and timing<br>of<br>Actigraphy   | R03   |
| A filter generates an alarm to be sent to INSERM screen if I <o 0.93.="" a="" after="" and="" below="" decreases="" determine="" during="" evaluated="" evolution="" has="" i<o="" if="" index="" is="" it="" level="" not.<="" of="" or="" period,="" r24="" risky="" sufficient="" system="" td="" the="" this="" time="" will=""><td>INSERM</td><td>The system should send an alert<br/>(On Screen Alert/SMS) to the<br/>operator (Nurse/Clinician/Case<br/>Manager) if there is a consistent</td><td></td><td></td></o> | INSERM   | The system should send an alert<br>(On Screen Alert/SMS) to the<br>operator (Nurse/Clinician/Case<br>Manager) if there is a consistent   |   |   |
| The system confirmed a consistent decrease of I <o (0.93)="" 24="" a="" alarm="" below="" during="" hours="" span;<="" td="" the="" threshold=""><td>INSERM</td><td>variation on the measurement,<br/>absolute or across time. The<br/>system should allow professional<br/>users to set rules about the limit of<br/>the variation (if more than XX UOM<br/>(UNIT OF MEASURE) across X<br/>continuous measurements/over XX<br/>days) to send the alert</td><td>Actigraphy<br/>Alerts</td><td>R07</td></o>                  | INSERM   | variation on the measurement,<br>absolute or across time. The<br>system should allow professional<br>users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alert   | Actigraphy<br>Alerts  | R07   |
| The company CareView (Denmark) has a video consulting service that runs over ADSL or 3G lines. Special buffering technology provides Quality of Service management.   | KGHNI  | The user should be provided with<br>AV Conference platform to get in<br>touch with the professional  | AV<br>Conferenc<br>e device   | R26   |
| Subjective input is provided via keyboard and video conferencing.   | KGHNI  | operators  |   |   |
| The video conferencing can be initiated either by the patient, in case of need, or by the doctor or nurse, in case of an alerted situation.   | KGHNI  | The system should allow the elderly<br>user or the professional user to<br>start a conference call   | Frequency<br>and timing<br>of AV<br>Connectio   | R27   |
| m TIth TInne Adevit TI  | he actigraph will transmit the recorded data by transmission to<br>the inCASA platform twice a day (early morning and late evening).<br>he rest-activity rhythm data are analysed daily through the I <o<br>dex. The daily changes in this parameter is assessed along the<br/>ecording process over 3 weeks or more.<br/>A filter generates an alarm to be sent to INSERM screen if I<o<br>ecreases below 0.93. After the system has evaluated the<br/>volution of the I<o a="" and="" during="" index="" period,<br="" r24="" sufficient="" time="">will determine if this level is risky or not.<br/>he system confirmed a consistent decrease of I<o below="" the<br="">larm threshold (0.93) during a 24 hours span;<br/>he company CareView (Denmark) has a video consulting service<br/>nat runs over ADSL or 3G lines. Special buffering technology<br/>rovides Quality of Service management.<br/>ubjective input is provided via keyboard and video conferencing.<br/>he video conferencing can be initiated either by the patient, in<br/>ase of need, or by the doctor or nurse, in case of an alerted</o></o></o<br></o<br> | INSERMINSERMhe actigraph will transmit the recorded data by transmission to<br>he inCASA platform twice a day (early morning and late evening).INSERMhe rest-activity rhythm data are analysed daily through the I <o<br></o<br> ndex. The daily changes in this parameter is assessed along the<br>ecording process over 3 weeks or more.INSERMA filter generates an alarm to be sent to INSERM screen if I <o<br></o<br> ecreases below 0.93. After the system has evaluated the<br>volution of the I <o a="" and="" during="" index="" period,<br="" r24="" sufficient="" time=""></o> will determine if this level is risky or not.INSERMhe system confirmed a consistent decrease of I <o below="" the<br=""></o> larm threshold (0.93) during a 24 hours span;INSERMhe company CareView (Denmark) has a video consulting service<br>nat runs over ADSL or 3G lines. Special buffering technology<br>rovides Quality of Service management.<br>ubjective input is provided via keyboard and video conferencing.KGHNI<br>KGHNI<br>KGHNIhe video conferencing can be initiated either by the patient, in<br>ase of need, or by the doctor or nurse, in case of an alerted<br>ituation.KGHNI | InstantINSERMSignal per limitehe actigraph will transmit the recorded data by transmission to<br>he actigraph will transmit the recorded data by transmission to<br>he inCASA platform twice a day (early morning and late evening).INSERMData should be transmitted to the<br>inCASA platform at least twice a<br>day. This frequency should be<br>customizable during the project.he rest-activity rhythm data are analysed daily through the I <o<br></o<br> ddex. The daily changes in this parameter is assessed along the<br>according process over 3 weeks or more.INSERMData should be transmitted to the<br>ustomizable during the project.<br>The system should allow<br>professional users to set the usual<br>timing of measurement (from<br>hh:mm to hh:mm) and the number<br>of measurements per dayA filter generates an alarm to be sent to INSERM<br>volution of the I <o a="" and="" during="" index="" period,<br="" r24="" sufficient="" time=""></o> will determine if this level is risky or not.INSERMThe system should send an alert<br>(On Screen Alert/SMS) to the<br>operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the measurement,<br>absolute or across time. The<br>system should allow professional<br>ues to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alerthe company CareView (Denmark) has a video consulting service<br>hart runs over ADSL or 3G lines. Special buffering technology<br>rovides Quality of Service management.KGHNIThe system should allow the elderly<br>user or the professional<br>user to get in<br>touch with the professional<br>user to get in<br>touch with the professional user to<br>start a conference call | InsteadInsteadSignal per minutehe actigraph will transmit the recorded data by transmission to<br>he inCASA platform twice a day (early morning and late evening).Data should be transmitted to the<br>inCASA platform at least twice a<br>day. This frequency should be<br>customizable during the project.Actigraphy<br>Data<br>Transmissi<br>onhe rest-activity rhythm data are analysed daily through the I <o<br></o<br> iddex. The daily changes in this parameter is assessed along the<br>ecording process over 3 weeks or more.INSERMINSERMChe with the project.Actigraphy<br>Data<br>Transmissi<br>onA filter generates an alarm to be sent to INSERM screen if I <o<br></o<br> ecreases below 0.93. After the system has evaluated the<br>volution of the I <o a="" and="" during="" index="" period,<br="" r24="" sufficient="" time=""></o> will determine if this level is risky or not.INSERMINSERMFrequency<br>and timing<br>of<br>measurement,<br>absolute or across time. The<br>system should allow professional<br>users to set rules about the limit of<br>the variation on the measurement,<br>absolute or across time. The<br>system should allow professional<br>users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alertActigraphy<br>Alertshe company CareView (Denmark) has a video consulting service<br>nat runs over ADSL or 3G lines. Special buffering technology<br>rovides Quality of Service management.<br>ubjective input is provided via keyboard and video conferencing.KGHNIThe system should allow the eldert<br> |

| Use Case<br>(Input) | Description   |       | Common Description  | Name                                 | Code<br>(Output) |
|---------------------|---|-------|---|--------------------------------------|------------------|
|                     |   |       |   | n                                    |                  |
| UC-KGHNI9           | Time and length of the video consultation is stored in a suitable Electronic Healthcare Record.   | KGHNI | All data should be stored on the<br>inCASA Repository through a<br>permanent internet connection  | AV<br>Conferenc<br>e Data<br>Storing | R06              |
| UC-ATC1             | contact sensor  | ATC   | The user's house should be<br>provided with wireless contact<br>sensor to detect opening/closing of<br>the front door   | The front<br>door<br>sensor          | R28              |
| UC-ATC1             | revelation of possible different patterns (User opens/closes the door; User goes out/stays in; User open the door, goes out and closes the door; User open the door, goes out without closing the door etc)   | ATC   | The system should allow<br>professional users to evaluate<br>changes from a "Normal Habits",<br>by building a "normal habits"<br>profile across 2 weeks of<br>monitoring  | Front door<br>Analysis               | R17              |
| UC-ATC1             | If the user forgets to close door, after going out or staying in, an<br>sms message of alert will be sent to neighbour/relative/social<br>worker; if the alert will not be successful, a an operator will be sent<br>to close the door and to do a survey | ATC   | The system should send an alert<br>(On Screen Alert/SMS) to the<br>operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the measurement,<br>absolute or across time. The<br>system should allow professional<br>users to set rules about the limit of<br>the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X<br>continuous measurements/over XX<br>days) to send the alert. The system<br>should allow professional users to<br>customize the system to send a<br>message to<br>user/relatives/caregiver/neighbour<br>if an emergency is detected | Front Door<br>Alert                  | R07<br>R11       |
| UC-ATC4             | sensors of temperature ad humidity  | ATC   | The user's house should be<br>provided with wireless humidity<br>and temperature sensors to detect<br>temp/moisture variations  | Comfort of<br>the home<br>sensors    | R29              |

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| Use Case<br>(Input) | Description   | Pilot | Common Description  | Name   | Code<br>(Output) |
|---------------------|---|-------|---|--|------------------|
| UC-ATC4             | the data coming from the flat will be sent continuously or periodically to the server   | ATC   | The system should allow<br>professional users to set the usual<br>timing of measurement (from<br>hh:mm to hh:mm) and the number<br>of measurements per day/week | Frequency<br>and timing<br>of<br>temperatu<br>re and<br>humidity<br>monitoring | R03              |
| UC-ATC4             | analysis of the gap between normal levels and revealed temperature and humidity   | ATC   | The system should send an alert<br>(On Screen Alert/SMS) to the   |  |                  |
| UC-ATC4             | operator (Nurse/Clinician/Case<br>Manager) if there is a consistent<br>variation on the measurement,<br>absolute or across time. The<br>cyctem chauld allow professional                                    |       | Comfort of<br>the home<br>alerts  | R07  |                  |
| UC-ATC5             | specific sensors  |       | The user's house should be<br>provided with wireless Gas-Water<br>leak/CO-Smoke Presence sensors<br>to detect emergency events                                  | Technical<br>emergenc<br>y sensors   | R30              |
| UC-ATC5             | The service shall provide an automatic set of alerts in case of water<br>or gas leaks, or from accidental fires, to avoid danger for the<br>security of the tenant/user                                     |       | The system should provide a continuous monitoring of the technical emergency sensors, forwarding the emergency signal in seconds after the event is detected    | Frequency<br>and timing<br>of<br>Technical<br>Emergenc<br>y<br>monitoring      | R31              |
| UC-ATC5             | If an emergency event is detected (water or gas leaks, smoke) an<br>immediate alert will be send through the Call centre to the closest<br>team of intervention or fireman service.                         | ATC   | The system should send an alert<br>(On Screen Alert/SMS) to the<br>operator (Nurse/Clinician/Case   |  |                  |
| UC-ATC5             | SMS, e-mail to the operator and acoustic/visual alert on the<br>operator UI<br>A message to the user/relatives/caregivers/neighbour can be sent<br>if there is an alert. This should be set by the operator |       | Manager) if an event is revealed.<br>The system should allow  | Technical emergenc   | R07<br>R11       |
| UC-ATC5             |   |       | professional users to customize the<br>system to send a message to<br>user/relatives/caregiver/neighbour<br>if an emergency is detected                         | y alerts   | N11              |

 Table 4 – Requirements Consolidation Step One

### 3.4 Consolidation Step Two

The second step of requirements consolidation focuses on the condensing of Step One requirements in order to derive at a common "platform" list of requirements (a mix of TeleCare and TeleHealth where possible) which will be prioritised and evaluated in relation to the risks for the first phase of the inCASA pilots.

The result of the "Step Two" of consolidation is shown on Table 5:

| Legenda |  |  |  |  |
|---------|--|--|--|--|
| TH      | TeleHealth                             |  |  |  |
| TC      | TeleCare                               |  |  |  |
| Tech    | Technological Requirement <sup>3</sup> |  |  |  |
| Func    | Functional Requirement                 |  |  |  |

| Code | Туре | Description  | ТН | тс |
|------|------|--|----|----|
| R01  | Tech | The user should be provided with a Bluetooth Weight Scale measuring in Kg  | Х  |    |
| R02  | Func | The system could send a reminder (sms or tablet alert) to the user to take measurement   | Х  |    |
| R03  | Func | The system should allow professional users to set the usual timing of measurement/assessment (from hh:mm to hh:mm) and the number of measurements/assessments per day  | х  | х  |
| R04  | Func | The system should accept extemporary measurements provided by the user/patient   | Х  | х  |
| R05  | Func | The system should allow measurement data visualization and extraction organized per day/per week/per month   | Х  | х  |
| R06  | Tech | All data should be stored on the inCASA Repository through a permanent internet connection   | Х  | х  |
| R07  | Func | The system should send an alert (On Screen Alert/SMS/e-mail) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurements or on the score of assessment, absolute or across time, or if an emergency event is revealed  | x  | х  |
| R08  | Tech | The user should be provided with a wireless pulse oximeter   | Х  |    |
| R09  | Func | The system should allow professional users to set rules: the<br>number of measurements to compare; the range of normality<br>and the limit of the variation (rough limit) to send the alert;<br>the limit of the variation (if more than XX UOM (UNIT OF<br>MEASURE) across X continuous measurements/over XX days)<br>to send the alert | Х  | х  |
| R10  | Func | The system could allow professional users to plan for single coded activities (e.g. medication change, appointment)  | х  | х  |
| R11  | Func | The system should be able to send SMS and e-mails. The system should allow professional users to customize the system to send a message to user/relatives/caregiver/neighbour if an event is revealed or an alert is triggered   | х  | х  |

<sup>&</sup>lt;sup>3</sup> Technological requirements are functionality needed purely because of the chosen technology. If the designer had selected a different technology to handle this part of the work, the result would be different.

| Code | Туре | Description   | TH | тс |
|------|------|---|----|----|
| R12  | Tech | The user should be provided with a Bluetooth blood pressure<br>Monitor measuring in mmHg with pulse metering capabilities   | Х  |    |
| R13  | Func | The system should allow professional users to set the number<br>of measurements to compare and the formula (e.g. average) to<br>be applied to the selected measurements   | Х  | Х  |
| R14  | Tech | The user should be provided with a Wireless Tablet connected to the inCASA platform   | Х  | Х  |
| R15  | Func | The system should allow the professional users to introduce<br>specific questions or questionnaires to be administered to the<br>patient and assign value to each answer and then calculate<br>scores                                   | х  |    |
| R16  | Func | The user's house should be provided by battery operated<br>wireless sensors to detect movement of the user inside the<br>house, recording time and duration of detected movement<br>events  |    | х  |
| R17  | Func | The system should allow professional users to evaluate<br>changes from a "Normal Habits", by building a "normal habits"<br>profile across 2 weeks of monitoring   | Х  | Х  |
| R18  | Func | The system should correlate movements to an algorithm made<br>to evaluate NYHA class of everyday activities, by taking into<br>account the movements, the number of people in the home as<br>well as subjective input from the patient. | х  | х  |
| R19  | Tech | The user's house should be provided by battery operated wireless sensors to detect presence of the user on the bed, recording time and duration of bed permanence events  |    | Х  |
| R20  | Tech | The user's house should be provided by battery operated wireless sensors to detect presence of the user on a chair, recording time and duration of chair permanence events  |    | Х  |
| R21  | Func | Data should be transmitted continuously to the inCASA platform or at least in 30" slots regularly or some times a day. This frequency should be customizable by the operator.   | Х  | Х  |
| R22  | Tech | Data should be stored on the standard cardiological repository of the KGHNI through integration with the inCASA platform  | Х  |    |
| R23  | Tech | The user should be provided with a glucose monitoring device  | Х  |    |
| R24  | Func | The user should be provided with a INR monitoring device or provided with a UI to insert manually measurements done with sticks   | Х  |    |
| R25  | Func | The user should be provided with Bluetooth actigraphs recording movement at a frequency of one signal per minute  | Х  | Х  |
| R26  | Tech | The user should be provided with AV Conference platform to get in touch with the professional operators   | х  | х  |
| R27  | Func | The system should allow the elderly user or the professional user to start a conference call  | Х  | Х  |
| R28  | Tech | The user's house should be provided with wireless contact sensor to detect opening/closing of the front door  |    | х  |
| R29  | Tech | The user's house should be provided with wireless humidity<br>and temperature sensors to detect temp/moisture variations  |    | Х  |
| R30  | Tech | The user's house should be provided with wireless Gas-Water leak/CO-Smoke Presence sensors to detect emergency events   |    | Х  |
| R31  | Func | The system should provide a continuous monitoring of the technical emergency sensors, forwarding the emergency signal in seconds after the event is detected  |    | Х  |
| R32  | Func | Data should be transmitted to the inCASA platform with a customizable frequency.  | Х  | Х  |
| R33  | Tech | The user should be provided with a wireless heart rhythm<br>Monitor with at least 3 electrodes measuring rhythm with a<br>basic EKG as output   | Х  |    |

Table 5 – Requirements Consolidation Step Two

This list of requirement will provide a good basis to develop the inCASA platform within WP3 activities. Each of the listed requirements are going to be technically described and turned into system specifications within D3.1. These will then be fed to developers and system integrators who will build the technical platform to deliver inCASA services.

# **4 User Requirements Prioritisation**

The consolidation of user requirements has now been produced. The realisation of time scale and resource constraints mean that the project will be delivered in an interactive way. Some requirements will be delivered within the first phase, and others will be planned for the next steps of the project. It is anticipated that there may be some aspects of the solution that may not be realised within the inCASA project life.

To plan for this, a prioritisation of the requirements collected must be performed that take into account the needs of the pilot sites, but also with respect to the technical and business partners, who may be trying to develop the parts of the process which are more effective to produce or significantly affect the business process.

After a survey of various methods concerning the prioritisation of requirements, the MoSCow method has been chosen as most suitable for the inCASA project's pilot partners (see paragraph 4.1). As the pilot partners are almost not technical, MoSCow method is easy to understand for them and is friendly to use because it shows directly how important each specific requirement is for each user. The requirements engineers and stakeholders should easily and quickly be able to understand the prioritization method as it clearly displays the priorities for all requirements.

Appendix A lists the other methods surveyed with a brief description of each.

But prioritisation is only part of the whole picture, given that all the scores assigned by MoSCoW method are signifying:

- what is critical to the project;
- what is needed but not critical;
- what can be left out

However, what is missing so far is a measurement of risk for a particular requirement. This led to introduce a method to quantify the amount of risk associated with a single requirement. Requirements Risk Assessment evaluates risks that are associated directly to specific requirements (see paragraphs 4.2 and 4.3). The inclusion or addition of a risk can have a number of impacts on a project's development.

The prioritisation of user requirements has to be realised by taking into consideration the workflow of the project and by evaluating the prioritisation and risk assessment made by each stakeholder type. In the next table each prioritisation method chosen is related to each kind of stakeholder:

| Method                   | Value(s)                     | Stakeholder(s)               |
|--------------------------|------------------------------|------------------------------|
| MoSCoW                   | ○ Must                       | Pilot Partners               |
|                          | <ul> <li>Should</li> </ul>   |                              |
|                          | <ul> <li>Could</li> </ul>    |                              |
|                          | <ul> <li>Wouldn't</li> </ul> |                              |
| Functional Risk          | ○ High                       | Pilot Partners and Technical |
|                          | <ul> <li>Medium</li> </ul>   | Partners                     |
|                          | o Low                        |                              |
| Regulatory/Business Risk | ○ High                       | Pilot Partners and Business  |
|                          | <ul> <li>Medium</li> </ul>   | Partners                     |
|                          | o Low                        |                              |

 Table 6 – Stakeholders for Requirements Prioritisation and Risk Assessment

# 4.1 MoSCoW

To clarify the aspects related to the inCASA requirements prioritisation it is good to describe the rules that were applied within the prioritisation activities. First of all should be taken in high consideration that project partners are not all technical, so a pragmatic and easy-to-understand method is needed. Therefore, in order to support agile development processes and rapidly changing requirements, the project team needs to be able to establish the prioritization represents a rapid and simple way to achieve this. MoSCoW is a method to prioritise requirements popularised by the DSDM<sup>4</sup> community. MoSCoW is an acronym which stands for:

- **M MUST** have this.
- **S SHOULD** have this if at all possible.
- **C COULD** have this if it does not affect anything else.
- **W WON'T** have this time but would like in the future.

The two lower case "o" is there just to make the acronym work. The importance of this method is that when prioritising the words mean something and can be used directly to discuss what is important for the various stakeholders.

The "Must" requirements are non-negotiable, if they are not delivered then the project is a failure, therefore it is in everybody's interest to agree what can be delivered and will be useful. Nice to have features are classified in the other categories of "Should" and "Could".

"Must" requirements must form a coherent set. They cannot just be "cherry picked" from all the others. If they are then what happens is that by default all the other requirements automatically become "Must", and the entire exercise is wasted.

Requirements marked as "Won't" are potentially as important as the "Must" category. It is not immediately obvious why this is so, but it is one of the characteristics that make MoSCoW such a powerful technique. Classifying something as "Won't" acknowledges that it is important, but can be left for a future release. In fact a great deal of time might be spent in trying to produce a good "Won't" list.

MoSCoW method has three important effects:

- Users do not have to fight to get something onto a requirements list;
- In thinking about what will be required later, affects what is asked for now;
- The designers seeing the future trend can produce solutions that can accommodate these requirements in a future release, and for the inCASA project this is a great point because of its future-related model.

Prioritisation will be during project development ensuring the essential work is completed within the given timeframe. Further, all the priorities will be reviewed throughout the project to ensure that they are still valid.

It is also essential to understand that not everything within the inCASA project is mandatory to be developed within the project life.

Prioritization activities according to the MoSCoW rules will be focused to enable the technical teams to deliver on time, by postponing the development of less critical requirements, selecting for first those requirements which will let the pilots to test and demonstrate the value of the inCASA solution. This index is filled by the Pilot Partners and is one of the most important project driver for the development of the inCASA solution.

### 4.2 Requirements Risk Assessment

As seen above, the process also needs to be able to quantify the amount of risk associated with a requirement. Requirements Risks are risks that are associated directly to specific requirements. The inclusion or addition of a risk can have a number of impacts on a project's risk profile. Certain requirements may open up risks of regulatory non-compliance, legal issues, unexpected costs or process bottlenecks and so on. In this case each requirement comes with a cost-benefit-risk profile, and each of those aspects needs to be considered when analysing requirements. Requirements can also have an impact on a project's capacity to deliver on its objectives. Consider an overworked project team which are asked to add on a few more features.

Risk can be measured in many different ways, but within inCASA it will be applied to two specific areas:

- Regulatory/Business Risk
- Functional Risk

**Regulatory/Business Risk** defines the impact on the business if the particular requirement is not delivered, or if a regulatory constraint or requirement is not met. For example if the system cannot meet a specific performance requirement and process the daily set of transactions then the business would be at risk of losing effectiveness, therefore customers and money. Criteria for Regulatory/Business Risk are listed on the next table:

| Class                                       | Criteria   |  |  |
|---|--|--|--|
| High (H)                                    | The requirement has direct impact on user/patient safety or  |  |  |
|   | system quality. Failure or inability to demonstrate compliance:  |  |  |
|   | <ul> <li>may result in non-working solution;</li> </ul>  |  |  |
|   | <ul> <li>may have significant social/health hazard;</li> </ul>   |  |  |
|   | <ul> <li>may cause a major financial loss due to a citation or</li> </ul>  |  |  |
|   | legal action.  |  |  |
| Medium (M)                                  | The requirement may indirectly affect user/patient safety or   |  |  |
|   | system quality. Failure or inability to demonstrate compliance   |  |  |
|   | <ul> <li>may result in repairable faults of the solution;</li> </ul>   |  |  |
|   | <ul> <li>may not exist significant or permanent social/health<br/>hazard;</li> </ul>   |  |  |
|   | <ul> <li>may cause some degree of financial loss due to losing</li> </ul>  |  |  |
|   | of potential customers.  |  |  |
| Low (L)                                     | The requirement has remote impact on user/patient safety or  |  |  |
|   | <ul> <li>system quality. Failure or inability to demonstrate compliance:</li> <li>will not result in social/health hazards or significant</li> </ul> |  |  |
|   |  |  |  |
|   | financial loss.  |  |  |
| Table 7 – Degulatory/Pupinges Dick Criteria |  |  |  |

Table 7 – Regulatory/Business Risk Criteria

**Functional Risk** defines the amount of risk on the implementation of the project to meet a specific requirement. For example a MUST requirement stating that the system must ensure the monitoring of a specific parameter, is functionally a high risk if it's not possible to implement it without a great effort to integrate device to the inCASA platform. Criteria for Functional Risk are listed on the next table:

| Class                              | Criteria  |  |
|------------------------------------|---|--|
| High (H)                           | Function/Requirement needs complex custom configuration   |  |
|                                    | or coding for integration or new development              |  |
| Medium (M)                         | Function/Requirement needs custom configuration or coding |  |
|                                    | for integration   |  |
| Low (L)                            | Function/Requirement doesn't need custom configuration or |  |
|                                    | coding to be integrated                                   |  |
| Table 8 – Functional Risk Criteria |   |  |

#### able 8 – Functional Risk Criteria

When combined, MoSCoW requirements prioritization and Business Risk quantification give a very easily implemented but useful mechanism for managing an ordered set of inCASA user requirements. The application of Functional Risk could finally normalize the criteria of prioritisation by considering technical effort.

### 4.3 Score Cards

Taking a leaf from the Agile Development<sup>5</sup> processes, the inCASA prioritisation team will involve the use of Score Cards. These are other easy-to-use measurement tools that show progress of an agile adoption and could be used iteratively. With Score Cards each requirement is written down on an index card. Each requirement can then be placed in a stack or Must, Should, Could, Won't. The first 3 can then have functional and regulatory/business risk ratings applied to them.

Assignment of values to each of the ratings:

| Code | Description              | Score |
|------|--------------------------|-------|
| 1    | Priority                 |       |
| 1.1  | Must                     | 5     |
| 1.2  | Should                   | 3     |
| 1.3  | Could                    | 1     |
| 1.4  | Won't/Would              | 0     |
| 2    | Regulatory/Business Risk |       |
| 2.1  | High                     | 5     |
| 2.2  | Medium                   | 3     |
| 2.3  | Low                      | 1     |
| 3    | Functional Risk          |       |
| 3.1  | High                     | 1     |
| 3.2  | Medium                   | 3     |
| 3.3  | Low                      | 5     |
|      |                          |       |
|      | Table 0 Seere Co         |       |

Table 9 – Score Card

Now it is possible to produce a total for each requirement which gives a range from 3 for a Could/Low/High to 15 for a Must/High/Low. The benefit of this approach also means that the focus is not 100% on business, but as well that high functional risk requirements are addressed well inside the project. The Team can then re-order their MoSCoW graded stacks into weighted scores and thereby know that the project is always managing and delivering the most needed requirements.

### 4.4 MoSCoW prioritisation

A specific "Prioritisation Pack" document has been sent to each Pilot Site and filled by them to prioritise the consolidated list of Functional and Technological Requirements. After the Pilot sites have stated their priority on the list of Requirements, an Average calculation have been applied on the different priorities, leading to have an average Total Score of MoSCoW.

<sup>&</sup>lt;sup>5</sup> Agile Modelling (AM) is a practice-based methodology for effective modelling and documentation of software-based systems. At a high level AM is a collection of best practices, depicted in the pattern language map below (click on the practice for information). At a more detailed level AM is a collection of values, principles, and practices for modelling software that can be applied on a software development project in an effective and light-weight manner (http://www.agilealliance.org).

An important rule has been applied while calculating the Average Total:

• If a Pilot Site stated a requirement as "Must": then the Average MoSCoW is "Must". This because this requirement has to be faced by the first phase of the project and if there is a Functional Risk or a Regulatory/Business Risk associated this could lead to have major problem with the requirement. But by the other side, an average calculation which doesn't take care of a "Must" requirement could lead to a possible failure of the pilot.

Table 10 below (page 38) shows the results of the MoSCoW prioritisation done by the Pilot Partners.

|        | Legenda   |
|--------|---|
| TH     | TeleHealth  |
| TC     | TeleCare  |
| Tech   | Technical Requirement   |
| Func   | Functional Requirement  |
| MoSCoW | Must=5; Should=3; Could=1; Wouldn't/Would=0                   |
| KGHNI  | Konstantopouleio General Hospital Nea Ionia (GR)              |
| INSERM | Institute National de la Santé et de la Recerche Médicale (F) |
| CHC    | Chorleywood Health Centre (UK)                                |
| ATC    | ATC Torino (I)  |
| AvTOT  | Average Total of MoSCoW across Pilot Partners                 |

| Code | Туре | Description  | ТН | тс | KGHNI | INSERM | СНС | ATC | AvTOT |
|------|------|--|----|----|-------|--------|-----|-----|-------|
| R01  | Tech | The user should be provided with a Bluetooth Weight Scale measuring in Kg  | Х  | -  | 5     | 5      | 5   | NA  | 5     |
| R02  | Func | The system could send a reminder (sms or tablet alert) to the user to take measurement   | Х  | -  | 3     | 1      | 3   | NA  | 3     |
| R03  | Func | The system should allow professional users to set the usual timing of measurement/assessment (from hh:mm to hh:mm) and the number of measurements/assessments per day  | х  | x  | 3     | 5      | 3   | 3   | 5     |
| R04  | Func | The system should accept extemporary measurements provided by the user/patient   | Х  | x  | 1     | 3      | 3   | NA  | 3     |
| R05  | Func | The system should allow measurement data visualization and extraction organized per day/per week/per month   | Х  | х  | 5     | 5      | 5   | 5   | 5     |
| R06  | Tech | All data should be stored on the inCASA Repository through a permanent internet connection   | Х  | x  | 5     | 5      | 5   | 5   | 5     |
| R07  | Func | The system should send an alert (On Screen Alert/SMS/e-<br>mail) to the operator (Nurse/Clinician/Case Manager) if there<br>is a consistent variation on the measurements or on the<br>score of assessment, absolute or across time, or if an<br>emergency event is revealed   | х  | x  | 5     | 5      | 5   | 5   | 5     |
| R08  | Tech | The user should be provided with a wireless pulse oximeter   | Х  | -  | 5     | 0      | 5   | NA  | 5     |
| R09  | Func | The system should allow professional users to set rules: the<br>number of measurements to compare; the range of<br>normality and the limit of the variation (rough limit) to send<br>the alert; the limit of the variation (if more than XX UOM<br>(UNIT OF MEASURE) across X continuous<br>measurements/over XX days) to send the alert | х  | x  | 1     | 5      | 5   | 5   | 5     |
| R10  | Func | The system could allow professional users to plan for single coded activities (e.g. medication change, appointment)  | х  | x  | 3     | 1      | 3   | 1   | 1     |
| R11  | Func | The system should be able to send SMS and e-mails. The system should allow professional users to customize the system to send a message to user/relatives/caregiver/neighbour if an event is revealed or an alert is triggered   | х  | x  | 3     | 3      | 3   | 3   | 3     |
| R12  | Tech | The user should be provided with a Bluetooth blood pressure<br>Monitor measuring in mmHg with pulse metering capabilities  | Х  | -  | 5     | 0      | 5   | NA  | 5     |

| R13 | Func | The system should allow professional users to set the number of measurements to compare and the formula (e.g. average) to be applied to the selected measurements   | х | х | 3  | 5  | 3  | 1  | 5 |
|-----|------|---|---|---|----|----|----|----|---|
| R14 | Tech | The user should be provided with a Wireless Tablet<br>connected to the inCASA platform  | Х | Х | NA | 5  | 3  | 0  | 5 |
| R15 | Func | The system should allow the professional users to introduce<br>specific questions or questionnaires to be administered to<br>the patient and assign value to each answer and then<br>calculate scores                                   | х | - | 1  | 5  | 3  | NA | 5 |
| R16 | Func | The user's house should be provided by battery operated<br>wireless sensors to detect movement of the user inside the<br>house, recording time and duration of detected movement<br>events  | - | х | 5  | 1  | 5  | 5  | 5 |
| R17 | Func | The system should allow professional users to evaluate changes from a "Normal Habits", by building a "normal habits" profile across 2 weeks of monitoring   | х | х | 5  | 1  | 5  | 5  | 5 |
| R18 | Func | The system should correlate movements to an algorithm<br>made to evaluate NYHA class of everyday activities, by<br>taking into account the movements, the number of people in<br>the home as well as subjective input from the patient. | х | х | 5  | 0  | 3  | 0  | 5 |
| R19 | Tech | The user's house should be provided by battery operated wireless sensors to detect presence of the user on the bed, recording time and duration of bed permanence events  | - | х | 5  | 1  | 5  | 5  | 5 |
| R20 | Tech | The user's house should be provided by battery operated<br>wireless sensors to detect presence of the user on a chair,<br>recording time and duration of chair permanence events  | - | х | 0  | 1  | 5  | 0  | 5 |
| R21 | Func | Data should be transmitted continuously to the inCASA platform or at least in 30" slots regularly or some times a day. This frequency should be customizable by the operator.   | х | х | 0  | 5  | 5  | 3  | 5 |
| R22 | Tech | Data should be stored on the standard cardiological<br>repository of the KGHNI through integration with the inCASA<br>platform  | х | - | 5  | NA | NA | NA | 5 |
| R23 | Tech | The user should be provided with a glucose monitoring device  | Х | - | 5  | 0  | 0  | NA | 5 |
| R24 | Func | The user should be provided with a INR monitoring device or provided with a UI to insert manually measurements done with sticks   | х | - | 5  | 0  | NA | NA | 5 |
| R25 | Func | The user should be provided with Bluetooth actigraphs recording movement at a frequency of one signal per minute  | Х | Х | NA | 5  | 0  | 0  | 5 |

| R26 | Tech | The user should be provided with AV Conference platform to get in touch with the professional operators  | х | х | 3  | 1  | NA | 0  | 1 |
|-----|------|--|---|---|----|----|----|----|---|
| R27 | Func | The system should allow the elderly user or the professional user to start a conference call   | Х | Х | 3  | 1  | NA | 0  | 1 |
| R28 | Tech | The user's house should be provided with wireless contact sensor to detect opening/closing of the front door   | - | х | 3  | 1  | NA | 3  | 3 |
| R29 | Tech | The user's house should be provided with wireless humidity<br>and temperature sensors to detect temp/moisture variations                                     | - | Х | NA | NA | NA | 5  | 5 |
| R30 | Tech | The user's house should be provided with wireless Gas-Water leak/CO-Smoke Presence sensors to detect emergency events  | - | х | NA | NA | NA | 3  | 3 |
| R31 | Func | The system should provide a continuous monitoring of the technical emergency sensors, forwarding the emergency signal in seconds after the event is detected | - | х | NA | NA | NA | 3  | 3 |
| R32 | Func | Data should be transmitted to the inCASA platform with a customizable frequency.   | Х | Х | 1  | 5  | 3  | 3  | 5 |
| R33 | Tech | The user should be provided with a wireless heart rhythm<br>Monitor with at least 3 electrodes measuring rhythm with a<br>basic EKG as output                | х | - | 5  | 0  | 0  | NA | 5 |

| Table 10 - | MoSCoW | Prioritisation |
|------------|--------|----------------|
|------------|--------|----------------|

## 4.5 Risk Assessment

Regulatory/Business Risk Assessment, for this first iteration, has been performed by partner INVENT. Functional Risk Assessment, for this first iteration, has been performed by technical partner NTUA taking into consideration the issues and topics discussed on the last technical Workshop in Brunel University (UK) on February, 2011. Some comments on the reasons for statement of Functional Risk have been introduced also by REPLY. Table 11 (page 42) shows the risk assessment.

|      | Legenda  |  |  |  |  |  |
|------|--|--|--|--|--|--|
| TH   | TeleHealth   |  |  |  |  |  |
| TC   | TeleCare   |  |  |  |  |  |
| Tech | Technical Requirement                              |  |  |  |  |  |
| Func | Functional Requirement                             |  |  |  |  |  |
| BR   | Regulatory/Business Risk - High=5; Medium=3; Low=1 |  |  |  |  |  |
| FR   | Functional Risk - High=1; Medium=3; Low=5          |  |  |  |  |  |

| Code | Туре | Description   | TH | ТС | FR | BR | Reasons   |
|------|------|---|----|----|----|----|---|
| R01  | Tech | The user should be provided with a Bluetooth<br>Weight Scale measuring in Kg  | Х  | -  | 5  | 3  | None  |
| R02  | Func | The system could send a reminder (sms or tablet alert) to the user to take measurement  | Х  | -  | 3  | 5  | None  |
| R03  | Func | The system should allow professional users to set<br>the usual timing of measurement/assessment (from<br>hh:mm to hh:mm) and the number of<br>measurements/assessments per day  | х  | x  | 3  | 3  | None  |
| R04  | Func | The system should accept extemporary measurements provided by the user/patient  | х  | х  | 3  | 1  | None  |
| R05  | Func | The system should allow measurement data visualization and extraction organized per day/per week/per month  | Х  | х  | 5  | 1  | None  |
| R06  | Tech | All data should be stored on the inCASA Repository through a permanent internet connection  | Х  | x  | 5  | 5  | None  |
| R07  | Func | The system should send an alert (On Screen<br>Alert/SMS/e-mail) to the operator<br>(Nurse/Clinician/Case Manager) if there is a<br>consistent variation on the measurements or on the<br>score of assessment, absolute or across time, or if<br>an emergency event is revealed  | х  | x  | 3  | 5  | None  |
| R08  | Tech | The user should be provided with a wireless pulse oximeter  | Х  | -  | 5  | 5  | None  |
| R09  | Func | The system should allow professional users to set<br>rules: the number of measurements to compare;<br>the range of normality and the limit of the variation<br>(rough limit) to send the alert; the limit of the<br>variation (if more than XX UoM (Unit of Measure)<br>across X continuous measurements/over XX days)<br>to send the alert | х  | x  | 1  | 5  | FR: Development complexity. This approach requires a storage of different rules parameters per patient. |
| R10  | Func | The system could allow professional users to plan for single coded activities (e.g. medication change, appointment)   | х  | x  | 5  | 5  | None  |
| R11  | Func | The system should be able to send SMS and e-<br>mails. The system should allow professional users<br>to customize the system to send a message to<br>user/relatives/caregiver/neighbour if an event is<br>revealed or an alert is triggered   | х  | x  | 3  | 5  | FR: Risk particularly for the SMS functionality (connect to an external SMS gateway and send the SMS)   |

| R12 | Tech | The user should be provided with a Bluetooth blood pressure Monitor measuring in mmHg with pulse metering capabilities   | х | - | 5 | 3  | None  |
|-----|------|--|---|---|---|----|---|
| R13 | Func | The system should allow professional users to set<br>the number of measurements to compare and the<br>formula (e.g. average) to be applied to the selected<br>measurements   | Х | х | 3 | 5  | FR: Development complexity.   |
| R14 | Tech | The user should be provided with a Wireless Tablet connected to the inCASA platform  | Х | х | 3 | 3  | FR: Depends on the functionality of the Tablet  |
| R15 | Func | The system should allow the professional users to<br>introduce specific questions or questionnaires to be<br>administered to the patient and assign value to<br>each answer and then calculate scores                                      | Х | - | 5 | 1  | None  |
| R16 | Func | The user's house should be provided by battery<br>operated wireless sensors to detect movement of<br>the user inside the house, recording time and<br>duration of detected movement events   | - | х | 1 | 3  | FR: Detection algorithm complexity. Need to<br>identify a single person's movement and<br>store complex data. Or to find a different<br>way to monitor the movement without<br>identifying the user |
| R17 | Func | The system should allow professional users to<br>evaluate changes from a "Normal Habits", by<br>building a "normal habits" profile across 2 weeks of<br>monitoring   | Х | х | 1 | 5  | FR: Computational Intelligence Algorithm may need extensive fine-tuning   |
| R18 | Func | The system should correlate movements to an<br>algorithm made to evaluate NYHA class of everyday<br>activities, by taking into account the movements,<br>the number of people in the home as well as<br>subjective input from the patient. | х | х | 1 | 5  | FR: Computational Intelligence Algorithm may need extensive fine-tuning   |
| R19 | Tech | The user's house should be provided by battery<br>operated wireless sensors to detect presence of the<br>user on the bed, recording time and duration of bed<br>permanence events  | - | х | 3 | 3  | FR: Presence detection is quite easy, while<br>time and duration recording may be more<br>challenging   |
| R20 | Tech | The user's house should be provided by battery<br>operated wireless sensors to detect presence of the<br>user on a chair, recording time and duration of chair<br>permanence events  | - | х | 3 | 3  | FR: Presence detection is quite easy, while<br>time and duration recording may be more<br>challenging   |
| R21 | Func | Data should be transmitted continuously to the<br>inCASA platform or at least in 30" slots regularly or<br>some times a day. This frequency should be<br>customizable by the operator.   | Х | х | 3 | NA | None  |

| R22 | Tech | Data should be stored on the standard cardiological repository of the KGHNI through integration with the inCASA platform  | х | - | 1 | NA | FR: Integration with an existing system that is inCASA agnostic may be challenging.   |
|-----|------|---|---|---|---|----|---|
| R23 | Tech | The user should be provided with a glucose monitoring device  | Х | - | 5 | 5  | None  |
| R24 | Func | The user should be provided with a INR monitoring device or provided with a UI to insert manually measurements done with sticks                                       | Х | - | 3 | 5  | FR: The manual insert process will need a streamlined GUI   |
| R25 | Func | The user should be provided with Bluetooth<br>actigraphs recording movement at a frequency of<br>one signal per minute  | х | х | 1 | 3  | FR: Bluetooth Actigraphs are evaluated , at<br>the moment, as hard to integrate into<br>inCASA platform from the technical partners |
| R26 | Tech | The user should be provided with AV Conference<br>platform to get in touch with the professional<br>operators   | Х | х | 3 | 3  | FR: Video quality depends on available<br>bandwidth. If ADSL line not in place, video<br>quality will be limited                    |
| R27 | Func | The system should allow the elderly user or the professional user to start a conference call  | Х | Х | 3 | 3  | None  |
| R28 | Tech | The user's house should be provided with wireless contact sensor to detect opening/closing of the front door  | - | Х | 5 | 1  | None  |
| R29 | Tech | The user's house should be provided with wireless<br>humidity and temperature sensors to detect<br>temp/moisture variations   | - | х | 5 | NA | None  |
| R30 | Tech | The user's house should be provided with wireless<br>Gas-Water leak/CO-Smoke Presence sensors to<br>detect emergency events   | - | х | 5 | NA | None  |
| R31 | Func | The system should provide a continuous monitoring<br>of the technical emergency sensors, forwarding the<br>emergency signal in seconds after the event is<br>detected | - | х | 1 | NA | FR: Continuous monitoring may not be possible in all configurations / scenarios.  |
| R32 | Func | Data should be transmitted to the inCASA platform with a customizable frequency.  | Х | Х | 3 | 3  | None  |
| R33 | Tech | The user should be provided with a wireless heart rhythm Monitor with at least 3 electrodes measuring rhythm with a basic EKG as output                               | х | - | 3 | 5  | None  |

Table 11 – Risk Assessment

## 4.6 Prioritisation Outcomes

The next table is a report of the outcomes of the common Prioritisation of the User Requirements for the first phase of inCASA project. The Formula is "Average Total Score of MoSCoW+Regulatory/Business Risk+Functional Risk.

|      | Legenda                             |
|------|-------------------------------------|
| TH   | TeleHealth                          |
| TC   | TeleCare                            |
| Tech | Technical Requirement               |
| Func | Functional Requirement              |
| TOT  | Average Total Score of MoSCoW+BR+FR |

| Code | Туре | Description  | TH | тс | тот |
|------|------|--|----|----|-----|
| R06  | Tech | All data should be stored on the inCASA Repository through a permanent internet connection   | Х  | х  | 15  |
| R08  | Tech | The user should be provided with a wireless pulse oximeter   | Х  |    | 15  |
| R23  | Tech | The user should be provided with a glucose monitoring device   | Х  |    | 15  |
| R01  | Tech | The user should be provided with a Bluetooth Weight Scale measuring in Kg  | Х  |    | 13  |
| R07  | Func | The system should send an alert (On Screen Alert/SMS/e-<br>mail) to the operator (Nurse/Clinician/Case Manager) if<br>there is a consistent variation on the measurements or on<br>the score of assessment, absolute or across time, or if an<br>emergency event is revealed | х  | х  | 13  |
| R12  | Tech | The user should be provided with a Bluetooth blood<br>pressure Monitor measuring in mmHg with pulse metering<br>capabilities   | Х  |    | 13  |
| R13  | Func | The System should allow professional users to set the<br>number of measurements to compare and the formula<br>(e.g. average) to be applied to the selected<br>measurements   | х  | х  | 13  |
| R24  | Func | The user should be provided with a INR monitoring device<br>or provided with a UI to insert manually measurements<br>done with sticks  | Х  |    | 13  |
| R33  | Tech | The user should be provided with a wireless heart rhythm<br>Monitor with at least 3 electrodes measuring rhythm with<br>a basic EKG as output  | Х  |    | 13  |
| R02  | Func | The system could send a reminder (sms or tablet alert) to the user to take measurement   | Х  |    | 11  |
| R03  | Func | The system should allow professional users to set the usual timing of measurement/assessment (from hh:mm to hh:mm) and the number of measurements/assessments per day  | Х  | х  | 11  |
| R04  | Func | The system should accept extemporary measurements provided by the user/patient   | х  | х  | 11  |
| R05  | Func | The system should allow measurement data visualization and extraction organized per day/per week/per month   | Х  | х  | 11  |

| R09 | Func | The system should allow professional users to set rules:<br>the number of measurements to compare; the range of<br>normality and the limit of the variation (rough limit) to<br>send the alert; the limit of the variation (if more than XX<br>UOM (UNIT OF MEASURE) across X continuous<br>measurements/over XX days) to send the alert | x | Х | 11 |
|-----|------|--|---|---|----|
| R10 | Func | The system could allow professional users to plan for single coded activities (e.g. medication change, appointment)  | х | х | 11 |
| R11 | Func | The System should be able to send SMS and e-mails. The system should allow professional users to customize the system to send a message to user/relatives/caregiver/neighbour if an event is revealed or an alert is triggered   | х | х | 11 |
| R14 | Tech | The user should be provided with a Wireless Tablet connected to the inCASA platform  | х | Х | 11 |
| R15 | Func | The system should allow the professional users to<br>introduce specific questions or questionnaires to be<br>administered to the patient and assign value to each<br>answer and then calculate scores  | х |   | 11 |
| R17 | Func | The System should allow professional users to evaluate changes from a "Normal Habits", by building a "normal habits" profile across 2 weeks of monitoring  | х | Х | 11 |
| R18 | Func | The system should correlate movements to an algorithm<br>made to evaluate NYHA class of everyday activities, by<br>taking into account the movements, the number of<br>people in the home as well as subjective input from the<br>patient.   | x | х | 11 |
| R19 | Tech | The user's house should be provided by battery operated<br>wireless sensors to detect presence of the user on the<br>bed, recording time and duration of bed permanence<br>events  |   | х | 11 |
| R20 | Tech | The user's house should be provided by battery operated<br>wireless sensors to detect presence of the user on a<br>chair, recording time and duration of chair permanence<br>events  |   | х | 11 |
| R32 | Func | Data should be transmitted to the inCASA platform with a customizable frequency.   | Х | Х | 11 |
| R29 | Tech | The user's house should be provided with wireless<br>humidity and temperature sensors to detect<br>temp/moisture variations  |   | Х | 10 |
| R16 | Func | The user's house should be provided by battery operated<br>wireless sensors to detect movement of the user inside<br>the house, recording time and duration of detected<br>movement events   |   | х | 9  |
| R25 | Func | The user should be provided with Bluetooth actigraphs recording movement at a frequency of one signal per minute   | х | Х | 9  |
| R28 | Tech | The user's house should be provided with wireless contact sensor to detect opening/closing of the front door   |   | х | 9  |
| R21 | Func | Data should be transmitted continuously to the inCASA platform or at least in 30" slots regularly or some times a day. This frequency should be customizable by the operator.  | х | Х | 8  |
| R30 | Tech | The user's house should be provided with wireless Gas-<br>Water leak/CO-Smoke Presence sensors to detect<br>emergency events   |   | Х | 8  |

| Tech | The user should be provided with AV Conference platform to get in touch with the professional operators  | х  | x  | 7  |
|------|--|--|--|--|
| Func | The system should allow the elderly user or the professional user to start a conference call   | Х  | Х  | 7  |
| Tech | Data should be stored on the standard cardiological repository of the KGHNI through integration with the X inCASA platform                                   |  |  | 6  |
| Func | The system should provide a continuous monitoring of the technical emergency sensors, forwarding the emergency signal in seconds after the event is detected |  | х  | 4  |
|      | Func<br>Tech   | Techto get in touch with the professional operatorsFuncThe system should allow the elderly user or the<br>professional user to start a conference callTechData should be stored on the standard cardiological<br>repository of the KGHNI through integration with the<br>inCASA platformFuncThe system should provide a continuous monitoring of the<br> | Techto get in touch with the professional operatorsXFuncThe system should allow the elderly user or the<br>professional user to start a conference callXTechData should be stored on the standard cardiological<br>repository of the KGHNI through integration with the<br>inCASA platformXFuncThe system should provide a continuous monitoring of the<br>technical emergency sensors, forwarding the emergency | Techto get in touch with the professional operatorsXXFuncThe system should allow the elderly user or the<br>professional user to start a conference callXXTechData should be stored on the standard cardiological<br>repository of the KGHNI through integration with the<br>inCASA platformXXFuncThe system should provide a continuous monitoring of the<br>technical emergency sensors, forwarding the emergencyX |

All the listed requirements are considered for the first phase of the project.

Applying this methodology technicians who are going to design and build the inCASA integrated platform have a common list of requirements prioritised following:

- 1. prioritisation provided by Pilot Sites, through an average of prioritisation;
- 2. Regulatory/Business Risk assessed by business partners;
- 3. Functional Risk application to balance the prioritisation, introducing the technical complexity as a criterion for the priority.

To evaluate the priority in relation to the single pilot site deployment, the project will look at each pilot site's prioritisation (see Table 10), then taking into consideration the related Risks, the deployment plan will be discussed directly with Pilot Representatives.

# **5 inCASA Core Requirements – the Habits Model**

The inCASA Platform takes advantages of existing products and integrates them to create an enhanced platform able to create a user habits model as the basis of a social care and healthcare model. Alerts can be generated in case of anomalous situations in respect to the created user habits model. The Core of the inCASA project is right the monitoring of User Habits, therefore the integrated has to be developed to satisfy this objective. That's why this chapter presents specific requirements for the habits model support, independently from the pilot's needs and "wants" to be developed on their countries.

## 5.1 The Habits Model

Through the use of an user habit monitoring system, user habit are monitored via small, wireless motion/contact sensors strategically placed in key areas like bedroom, kitchen, bathroom to record and report related user activity to create a dedicated user habits model (e.g. Bathroom visits during the day and during the night).

The next table (Table 13) shows the specific requirements of the Habits Model within the inCASA platform. Such requirements have not to be prioritised by pilot sites or evaluated by the Risk, because we are listing "in detail" the Core requirements of the project about habits monitoring: high level and common functional requirements have been already prioritised within the requirements consolidation and prioritisation section of this deliverable (see chapter 3 and 4).

Description To profile user habits for a certain period A "User Habit" is defined as the repeating of a single or complex action (like sitting on a chair or going out of home) or a pathway (a **Definition 1** sequence of actions like going out of bedroom to toilet every day after getting up from bed) for several times at about the same time during a week. The system should register any single action coming from the User's **HM-R01** house for a week (the time frame should be configurable), including the time stamp of the events. Habits Models. The system should create a profile of actions and pathways defined as "Normal Habits Model", by measuring and profiling the next **HM-R02** actions/pathways: Going to bed/Wake up: time stamp for going to bed and getting up HM-R02a from bed with DeltaT between the time stamps. Going out from home: time stamp for going out of home/coming HM-R02b back to home with DeltaT between time stamps Moving inside home: number of movements inside the house and HM-R02c time stamp/location of each movement detected by sensors The system should check the variations of the Normal Habits Model **HM-R03** for 2 weeks after the first profiling to allow a first iterative "tuning" of the model.

Note that HM-Rxx is for "Habits Monitoring Requirement No. xx"

On the next table (Table 14) a description of how the habits model alerts system specification is presented:

|            | Description  | To manage alerts and emergencies related to habits model   |
|------------|--------------|--|
| ts         | Definition 1 | "Alert" is defined as a message triggered by an event out of "normal<br>habits profile" or an "emergency" event, with relevance for the<br>operator and which needs an action. |
| ing alerts | HM-R04       | The system should describe alerts with: identification – name – description – priority – severity.   |
| monitoring | HM-R05       | The system should consider as priority: non urgent – mild urgent – urgent – very urgent – emergency.   |
| Habits m   | HM-R06       | The system should show a list of the users and related alert ordered per priority/per severity/per time.   |
| Ĩ          | HM-R07       | The system should enable a method on the GUI to mark the alert as "forwarded to (select role)" or "solved".  |
|            | HM-R08       | The system should permit the opening of an user dedicated page on which single alert is described.   |

 Table 14 – Specific detail of Habits Monitoring Alerts Requirements

## 5.2 inCASA Habits Monitoring – the Service Delivery Model

To introduce the Service Delivery model within the inCASA project, first we would like to state that the supposed models may change significantly during the project due to the influence of the results from the monitoring of user habits, changes within the local Healthcare and Social Care systems, market changes, as well as due to the reaction and experiences of the users (elderly users and professionals).

The process implemented in the Habits Monitoring Use Cases will profile user habits in order to automatically identify anomalous situations and send alert to the user, carers and to the Service Provider. So, Healthcare and Social Care professional users will be able to take the right decision and to plan interventions to prevent risks related to the single user (Case Management).

The next scenarios, based on the ATC pilot implementation are made to exemplify workflows related to a specific service delivery model which would need automatic workflows or operator quick response. All the parameters and ranges will be customizable by operators through a specific Service User Interface.

#### 5.2.1 Scenario 1: Door

This scenario describes the management of the front Door of user's house.

Process to be evaluated:

- User opens/closes the door
- User goes out/stays in
- User open the door, goes out and closes the door
- User open the door, goes out without closing the door
- User open the door, doesn't go out and closes the door

• User open the door, doesn't go out and doesn't close the door

#### Habits model alerts:

1. User forgets to close door, after going out or staying in:

Actions:

- a. If he stays at home → after 1-180 mins → open door acoustic alert → if he closes door → alert stop → if doesn't close door → after 1-180 mins → SMS to relative/neighbour → if he closes door → alert stop → if doesn't close door → after 1-180 mins → alert message to Operator → user phone call + relative/neighbour call → if success → alert stop → if not success → send an operator/technician to close the door and verify user conditions
- b. If he goes out → while going away → open door acoustic alert → if he closes door → alert stop → if doesn't close door → after 1-180 mins → SMS to relative/neighbour → if he closes door → alert stop → if doesn't close door → after 1-180 mins → alert message to Operator → user phone call + relative/neighbour call → if success → alert stop → if not success → send an operator/technician to close the door and verify user conditions
- 2. User is not going out for several days/weeks:

#### Actions:

- a. If before he used to usually going out (every day or regularly) → after 1-90 days → alert to the Operator (User is not going out since 1-90 days ago) → user phone call → if success → alert stop → if not success → relative/neighbour call → if success → alert stop → if not success → after 1-90 days → social/psychological support activation → visit to the user
- b. If before he used not to usually going out (every day or regularly) → after 1-90 days → alert to the Operator (User is not going out since 1-90 days ago) → user phone call → if success → alert stop → if not success → relative/neighbour call → if success → alert stop → if not success → after 1-90 days → social/psychological support activation → visit to the user
- 3. User doesn't open door for several days:

#### Actions:

- a. If he used to open door usually without going out (= incoming visits) → after 1-90 days → alert to the Operator (user is not opening door since 1-90 days ago) → user phone call + SMS to relative/neighbour → if success → alert stop → if not success → relative/neighbour call → if success → alert stop → if not success → after 1-90 days → social/psychological support activation → visit to the user
- b. If he used not to open door usually without going out (= no visits) → after 1-90 days → alert to the Operator (user is not opening door since 1-90 days ago) → user phone call + SMS to relative/neighbour → if success → alert stop → if not success → relative/neighbour call → if success → alert stop → if not success → after 1-90 days → social/psychological support activation → visit to the user
- 4. User goes out closing/not closing the door and does not get back home at night:

- a. If he informed Operator → set the scheduled time for coming back → no action → if he gets back within scheduled date → platform records when he gets back → if he doesn't get back within the scheduled date → after 00.00 23.59 of the scheduled date → SMS + call to relative/neighbour → if success → alert stop → if not success → call to emergency services
- b. If he did not inform Operator  $\rightarrow$  after 00.00 23.59 of the outgoing date  $\rightarrow$  SMS + call to relative/neighbour  $\rightarrow$  if success  $\rightarrow$  alert stop  $\rightarrow$  if not success  $\rightarrow$  call to emergency services

#### 5.2.2 Scenario 2: Indoor movement

This scenario describes the management of the movement related to user's house. Note that this is not a TeleEmergency use case. There is no direct or real-time information about user conditions if a personal health device is not worn.

Process to be evaluated:

- User is moving inside his home
- User is not moving inside his home

#### Habits model alerts:

1. User is not moving for several hours (> 50% of usual movement):

Actions:

- a. User is not moving → after 1-180 hours → if no other actions meaning he is doing something → alert message to Operator → user phone call + relative/neighbour call → if success → alert stop → if not success → send an operator to verify user conditions
- 2. User is moving inside his home abnormally:

Actions:

- a. User is moving continuously → after 1-180 hours of continuous movement → alert message to Operator → user phone call + relative/neighbour call → if success → alert stop → if not success → send an operator to verify user conditions
- b. User is moving during night (while he normally sleeps during night) → after 1-999 movement events detection (means no occasional wake up) → alert message to Operator → next day user phone call (it depends on single case) → if success → alert stop → if not success → send an operator to verify user conditions

#### 5.2.3 Scenario 3: Bed permanence

This scenario describes control of bed permanence.

Process to be evaluated:

- User goes to bed
- · User stays on bed
- User wakes up from bed
- User doesn't go to bed

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#### Habits model alerts:

1. User is staying on bed less/more than usual:

Actions:

- a. User is staying on bed longer than usual → after 1-180 hours → alert message to Operator
   → user phone call + relative/neighbour call → if success → alert stop → if not success
   → send an operator to verify user conditions
- b. User is staying on bed shorter than usual → after 1-90 days of reduced permanence on bed than usual (>1-24 hours of reduction of permanence on bed for more than 1-30 continuous days) → alert message to Operator → user phone call + relative/neighbour call → if success → alert stop → if not success → send an operator to verify user conditions
- 2. User is waking up from bed during night more than usual:

#### Actions:

- a. User is waking up from bed during night → after 1-99 wake up events detection (means no occasional wake up) → alert message to Operator → next day user phone call + relative/neighbour call → if success → alert stop → if not success → send an operator to verify user conditions
- b. User is going to bed at unusual time (e.g. in late morning) → after 1-90 days of repeating unusual (>1-999 "going to bed" events detected on 1-90 continuous days or (>1-99 "going to bed" events detected on a single week) → alert message to Operator → prompt for user phone call + relative/neighbour call → if success → alert stop → if not success → send an operator to verify user conditions

## **6 Non Functional Requirements**

Non-functional requirements are properties the functionality must have [5]. The functionality can be represented either by a use case or by a functional requirement. Some of them can be linked directly to a functional requirement, some apply to the use case as a whole, and some apply to the entire platform.

Following are the non-functional requirement types considered by the inCASA project, according to the Volere Requirements Specification<sup>2</sup>.

The list is not complete due to the iterative nature of the project, therefore it will be updated regularly.

- Look and Feel: the spirit of the product's appearance
- Usability and Humanity: the platform's ease of use, and any special usability considerations needed for a better user experience
- **Performance:** how fast, how safe, how many, how available, and how accurate the functionality must be
- **Operational:** the operating environment of the solution, and any considerations that must be taken into account for this environment
- Maintainability and Support: expected changes, and the time needed to make them; also specification of the support to be given to the platform
- **Security:** the security, confidentiality, and recoverability of the platform
- **Cultural and Political:** special requirements that come about because of the culture and customs of people involved in the platform's operation
- Legal: the laws and standards that apply to the platform.

## 6.1 Look and Feel Requirements

- The main interface of the inCASA platform for the Operators will be Web Based and should give the user different options to move through the system, using navigation methods such as menus and buttons;
- The system should display and manage both the clinical monitoring data and habits monitoring data within the same application;
- One main button should allow the user to return to the main menu or home page from anywhere inside the application;
- The web site should be structured in a hierarchical manner containing various subinterfaces;
- The sub-interface should have buttons which will link to different sub-interfaces depending on the privileges of the user;
- On this screen a home button should take the user back to the main interface screen;
- The Interface may include a small logo of inCASA project;
- The colour to be used in the background should not induce stress to the user;
- the text should be black, no bright colours such red or orange would be used for background colours, however can be used to highlight text i.e. for Alerts.

## 6.2 Usability and Humanity Requirements

- The inCASA platform will be very simple and easy to use;
- The overall system Interface would be easily used by people with basic computer systems training and with little understanding of English;

- The system should be designed in a way that makes it easy for user to remember the steps they should follow;
- Ideally, the system should be free of errors, but in case that the users do something wrong the errors messages should be indicated in plain English, in that way, it will be easier for users to understand what they are doing wrong when using the system;
- Where a patient/elderly user interface is involved, the system should be localised on the language of the users;
- Where a patient/elderly user interface is involved, the system should provide an interface that is large enough for an elderly person to view the screen clearly: Large display; Font size; lcons; Easily readable;
- Where a patient/elderly user interaction is needed, the system should provide clear instructions to the user/patient;
- Where a patient/elderly user interaction is needed, the system should be able to display simple list of questions for the chosen disease categories/social challenges;
- Where a patient/elderly user interaction is needed for taking measurements, the system should be able to display health monitoring feedback to the user/patient;
- Where a patient/elderly user interaction is needed for taking measurements, the system should be able to provide a means for manual input of measurement data/responses to questions;
- the system should be able to provide audible feedback for people with visual impairments.

#### 6.3 Performance Requirements

Speed and latency

• Interfaces will count on an advanced remote system that will allow a maximum response time of 10 seconds for the most complicated actions (Formulae application or data extraction).

Safety Critical requirements

- The system will be very safe, International certification of EC is present on each of the off-shelf devices, and thus no risks are foreseen for the users, their homes or to the environment;
- If prototypes are involved, a specific declaration of safety and conformity will be released by the partner who provides the prototype, declaring that no risks are foreseen risks for the users, their homes or the environment.

Reliability and availability requirements

- The aim of the inCASA platform is to deliver a very reliable product with minimal degree of failures, therefore minimal maintenance is required;
- The system will be available for use 24 hours per day, 365 days per year;
- The operators will be available in accordance with local agreements.

Robustness requirements

- Each device communicates wireless with the home gateway;
- The devices should transmit data via the internet or mobile communications;
- If interrupted during transmission, the home gateway will store the data until it is able to re-send data;

- The system should operate on both main power and battery power;
- In the event of a power outage the system should automatically reset without the need for user intervention.

Capacity Requirements

• The system should allow a maximum of 30 houses connected at the same time per pilot site (for the pilot duration). It will be designed to be able to connect simultaneously up to 500 users' houses at any time of the day.

Scalability or extensibility requirement

- Due to the nature of the system, the capacity of processing information is indefinite;
- The system should be designed to ensure scalability and access to incoming new technologies like Cloud Computing;

#### 6.4 Operational Requirements

Expected physical environment:

- This system with its actual configuration must be installed indoor (sensors/devices);
- The devices shall survive being dropped;
- The devices shall conserve battery life;

Expected technological environment:

- The system will initially run on desktops or laptops with a minimum 512 of RAM and 40 GB and 400 MHz processor, with a Web Browser installed;
- In the future the inCASA platform should be accessed through smart phones, palmtops, Pads, etc., therefore increasing technological support should be taken into consideration during the design activities.

## 6.5 Maintainability and Support Requirements

Ease of maintaining the inCASA solution

- The maintenance of the system should be ensured by a local network of technicians and the local availability of solution's parts;
- Devices should be assigned to the user by device serial number;
- For each device the location e.g. which room the sensors are placed, should be entered;
- A complete list of monitoring equipment should be available electronically, which can be sorted by: Device Type; Serial Number; Assigned; Unassigned; Faulty.

Supportability

- The level of support this system will require should be very low;
- An help desk should be made available to provide the necessary support;
- The system should have some help tabs in the main User Interface.

Portability Requirements

• According to the fact that the system is web based with its target browser being MS Internet Explorer, it would be expected to run across various web browsers like Firefox or Safari.

#### 6.6 Security Requirements

These requirements have a HIGH priority and are addressed by the beginning of the design of the solution phase.

Confidentiality Requirements

- The system shall ensure that only authorized users have access to the patient/user data;
- All the authorized personnel will have access to the system, but only the Administrator will have rights to either add new users or delete the ones that are leaving;
- The inCASA system web server shall be password protected where appropriate to allow only pertinent inCASA team members access;
- The inCASA system shall deliver data in a manner that prevents further or secondhand use by unauthorized people.

Integrity requirements

• The system should prevent its data from incorrect usage and prevent unintentional misuse by authorized users.

Privacy requirements

- The system should preserve privacy of personal health care data both for user acceptance and for the credibility of the entire health systems;
- Devices and inCASA platform will therefore have to comply with national legislation regarding access to patient data, both sensitive and non-sensitive.

## 6.7 Political and Cultural Requirements

- The system shall not display religious symbols or words associated with mainstream religions;
- The system shall not use any terms or icons that might possibly offend anyone on the planet.

# 6.8 Legal Requirements (for further information please refer to D2.1 preliminary requirements investigation)

These requirements have a HIGH priority and are addressed by the beginning of the design of the solution phase.

 inCASA technologies and application will have the necessary security measurements in order to protect privacy and personal data. Informed consent forms will be obtained from all end-users trying to address the most of the European and local laws and directives:

- The European Convention for the Protection of Human Rights and Fundamental Freedoms;
- EU Charter of Fundamental Rights;
- Directive 95/46/EC on processing personal data;
- Directive 2002/58/EC on data protection;
- Directive 2006/24/EC on data protection;
- Law of the 6th January 1978, concerning data processing, files and freedom (France);
- Law of the 6th of August 2004 (modifying the above law), concerning protection of individuals with regard to personal data processing (France);
- Personal Data Protection Act, 2472/97 (Greece);
- Data Protection Authority, Regulations 408, 1/99: Notification of subjects about recording personal data (Greece);
- 2774/1999: Personal data protection in telecommunications (Greece);
- Tutela delle persone e di altri soggetti rispetto al trattamento dei dati personali Legge n. 675 del 31 Dicembre 1996, G.U. n. 5 dell'8 Gennaio 1997 (Italy);
- DL 196/2003 (Italy);
- Data Protection Act 1998 (UK);
- Freedom of Information Act 2002 (UK);
- Freedom of Information Act (Scotland) 2002 (UK).
- The inCASA platform supports interoperability addressing:
  - Directive on the application of patients' rights in cross-border healthcare;
    - A Digital Agenda for Europe.
- The medical devices that are going to be used as part of inCASA service will be in compliance with 2007/47/EEC Medical Device Directives;
- The inCASA system will comply European and International Standards Requirements (for further information please refer to inCASA D2.1 document).

# 7 Conclusions

This document is a first iteration of a wider process to build a strong platform to develop the inCASA solution. The user-centred approach, ensured by the process of validation and user-weighted requirements engineering process could assure a wider penetration and acceptance of the service delivered by matching user needs much more than using a "top to bottom" methodology.

The requirements of the first phase of the project have been extracted, consolidated and prioritised to feed the technical work, defining also the devices to be introduced on each pilot site and the services to be deployed in each country. Non functional requirements have been considered and stated for the inCASA solution.

In the next iteration there will be a refinement of the requirements, by describing the second phase requirements according to the outcomes of the pre-pilot phase and of the first phase of pilot activities.

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# 9 Appendix A: Candidate Prioritization Methods

A number of prioritization methods have been found to be useful in requirements engineering and could potentially be used for inCASA requirements. We briefly mention here the Binary Search Tree, Numeral Assignment Technique, Planning Game, the 100-Point Method, Theory-W, Requirements Triage, Wiegers' Method, Requirements Prioritization Framework, and AHP.

## 9.1 Binary Search Tree (BST)

Binary Search Tree is an algorithm that is typically used in a search for information and can easily be scaled to be used in prioritizing many requirements [20]. The basic approach for requirements is as follows, quoting from [20]:

- 1. Put all requirements in one pile.
- 2. Take one requirement and put it as root node.
- 3. Take another requirement and compare it to the root node.
- 4. If the requirement is less important than the root node, compare it to the left child node. If the requirement is more important than the root node, compare it to the right child node. If the node does not have any appropriate child nodes, insert the new requirement as the new child node to the right or left, depending on whether the requirement is more or less important.
- 5. Repeat steps 3-4 until all requirements have been compared and inserted into the BST.
- 6. For presentation purposes, traverse through the entire BST in order and put the requirements in a list, with the least important requirement at the end of the list and the most important requirement at the start of the list.

## 9.2 Numeral Assignment Technique

The Numeral Assignment Technique provides a scale for each requirement. Brackett proposed dividing the requirements into three groups: mandatory, desirable, and unessential [21]. Participants assign each requirement a number on a scale of 1 to 5 to indicate its importance [22]. The numbers carry the following meaning:

- 1. does not matter (the customer does not need it)
- 2. not important (the customer would accept its absence)
- 3. rather important (the customer would appreciate it)
- 4. very important (the customer does not want to be without it)
- 5. mandatory (the customer cannot do without it)

The final ranking is the average of all participants' rankings for each requirement.

## 9.3 Planning Game

The planning game is a feature of extreme programming [23] and is used with customers to prioritize features based on stories. This is a variation of the Numeral Assignment Technique, where the customer distributes the requirements into three groups, "those without which the system will not function," "those that are less essential but provide significant business value," and "those that would be nice to have."

#### 9.4 100-Point Method

The 100-Point Method [24] is basically a voting scheme of the type that is used in brainstorming exercises. Each stakeholder is given 100 points that he or she can use for voting in favour of the most important requirements. The 100 points can be distributed in any way that the stakeholder desires. For example, if there are four requirements that the stakeholder views as equal priority, he or she can put 25 points on each. If there is one requirement that the stakeholder views as having

overarching importance, he or she can put 100 points on that requirement. However, this type of scheme only works for an initial vote. If a second vote is taken, people are likely to redistribute their votes to get their favourites moved up in the priority scheme.

#### 9.5 Theory-W

Theory-W was initially developed at the University of Southern California in 1989 [25,26]. It is also known as "Win-Win." An important point is that it supports negotiation to solve disagreements about requirements, so that each stakeholder has a "win." It has two principles:

- 1. Plan the flight and fly the plan.
- 2. Identify and manage your risks.

The first principle seeks to build well-structured plans that meet predefined standards for easy development, classification, and query. "Fly the plan" ensures that the progress follows the original plan. The second principle, "Identify and manage your risks," involves risk assessment and risk handling. It is used to guard the stakeholders' "win-win" conditions from infringement. In win-win negotiations, each user should rank the requirements privately before negotiations start. In the individual ranking process, the user considers whether there are requirements that he or she is willing to give up on, so that individual winning and losing conditions are fully understood. Theory-W has four steps:

- 1. Separate the people from the problem.
- 2. Focus on interests, not positions.
- 3. Invest options for mutual gain.
- 4. Insist on using objective criteria.

#### 9.6 Requirements Triage

Requirements Triage [27] is a multi step process that includes establishing relative priorities for requirements, estimating resources necessary to satisfy each requirement, and selecting a subset of requirements to optimize probability of the product's success in the intended market. This is clearly aimed at developers of software products in the commercial marketplace. Davis's more recent book [28] expands on the synergy between software development and marketing. It is a unique approach that is worth reviewing, although it clearly goes beyond traditional requirements prioritization, considering business factors as well.

#### 9.7 Wiegers' Method

This method relates directly to the value of each requirement to a customer [29]. The priority is calculated by dividing the value of a requirement by the sum of the costs and technical risks associated with its implementation [29]. The value of a requirement is viewed as depending on both the value provided by the client to the customer and the penalty that occurs if the requirement is missing. This means that developers should evaluate the cost of the requirement and its implementation risks, as well as the penalty incurred if the requirement is missing. Attributes are evaluated on a scale of 1 to 9.

#### 9.8 Requirements Prioritization Framework

The requirements prioritization framework and its associated tool [30, 31] includes both elicitation and prioritization activities. This framework is intended to address the following:

- $\circ$   $\,$  elicitation of stakeholders' business goals for the project
- $\circ$   $\;$  rating the stakeholders using stakeholder profile models

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- allowing the stakeholders to rate the importance of the requirements and the business goals using a fuzzy graphic rating scale
- o rating the requirements based on objective measure
- finding the dependencies between the requirements and clustering requirements so as to prioritize them more effectively
- using risk analysis techniques to detect cliques among the stakeholders, deviations among the stakeholders for the subjective ratings, and the association between the stakeholders' inputs and the final ratings

## 9.9 AHP

AHP is a method for decision making in situations where multiple objectives are present [32, 33, 34]. This method uses a "pair-wise" comparison matrix to calculate the relative value and costs of individual security requirements to one another. By using AHP, the requirements engineer can confirm the consistency of the result. AHP can prevent subjective judgment errors and increase the likelihood that the results are reliable. AHP is supported by a standalone tool, as well as by a computational aid within the SQUARE tool.

There are five steps in the AHP method:

- 1. Review candidate requirements for completeness.
- 2. Apply the pair-wise comparison method to assess the relative value of each of the candidate requirements.
- 3. Apply the pair-wise comparison method to assess the relative cost of the candidate requirements.
- 4. Calculate each candidate requirement's relative value and implementation cost, and plots each on a cost-value diagram.
- 5. Use the cost-value diagram as a map for analyzing the candidate requirement.