
**ESTABLISHMENT OF A SOFTWARE ARCHITECTURE FOR HEALTH CARE SUPPORTIVE
HOME SYSTEM TO ASSIST PATIENTS WITH DIABETES MELLITUS:
FUNCTIONAL AND NON-FUNCTIONAL REQUIREMENTS**

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Establishment of a Software Architecture for Health Care Supportive Home System to Assist Patients with Diabetes Mellitus: Functional and Non-Functional Requirements

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1.0		Technical Report	Vicente, I. Z.	Release of the technical report.

Abstract

Ambient Assistive Living (AAL) aims to improve the quality of life of the population by using different technologies to assist people with special needs. In particular, Healthcare Supportive Home (HSH) System, a special type of AAL systems, give us home care methods for continuous monitoring of health conditions, transforming people's life to a more comfortable and independent one. The objective of this document is to present the result of the first phase of the Initiation Project supported by FAPESP (Grant: 2017/01672-3), during which we define the functional and non-functional requirements of DiaManT@Home, a Healthcare Supportive Home (HSH) System to assist the management of patients diagnosed with Diabetes Mellitus.

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1 Introduction

Diabetes Mellitus is a life-long health condition (also denominated as chronic condition) that causes high concentration of glucose in the blood [1]. The most common types of diabetes can be caused by a deficiency in the insulin production by the pancreas (Type 1 Diabetes), or also when the production of the insulin is not enough or the person has an insulin resistance (Type 2 Diabetes) [1]. The foundation of the treatment and prevention of diabetes lays on reeducation about dieting, exercising, monitoring sugar levels, and medication to prevent complications caused by high levels of glucose in the blood, such as cardiovascular diseases (i.e. conditions that involve heart and blood vessels), retinopathy (i.e. damage in the retina of the eyes), neuropathy (i.e. general diseases of the nerves), and nephropathy (i.e. disease or damage of the kidney) [2].

In this perspective, new methods, products, and services, as those provided by the Ambient Assisted Living (AAL) domain [3], for supporting activities of daily life of people with chronic diseases are effective to assist the management of diabetes disease. In particular, as defined by Garcés et al. [4], “HealthCare Supportive Home (HSH) systems are a special type of AAL systems that can provide an autonomous life in their residence to patients and supply them with autonomy through the use of different types of technologies, such as smart homes, Ambient Intelligence (AmI), electronic health (eHealth), sensor networks, assistance robots, advanced human/machine interfaces, Internet of Things (IoT), microelectronics, and web&network technologies” [4].

In this technical report, we present results of establishing functional and non-functional requirements for DiaManT@Home, a system that assists patients with diabetes mellitus for the management of their condition at home. Requirements presented herein were obtained during the execution of the first phase of the Initiation Project supported by FAPESP (Grant: 2017/01672-3).

For identifying functional requirements, we use guidelines offered by the Brazilian Diabetes Society (Sociedade Brasileira de Diabetes) and the American Diabetes Association [1, 5], and guidelines offered by experts. The QM4AAL, a quality

model for AAL systems proposed by Garcés et. al [8,9] was used to identify the requirements of quality attributes. The requirements document was refined through several iterations conducted during group meetings. Finally, a categorization of requirements was made to classify them regarding its possible impact in the DiaManT@Home software architecture.

The remainder of this document is organized as follow: Section 2 presents the Stakeholders of DiaManT@Home. The functional requirements are presented in Section 3. Section 4 describes the non-functional requirements of such system. Section 5 defines a mapping between functional and non-functional requirements. Finally, in Section 6 final remarks are discussed.

2 Stakeholders

In this section we present and define the stakeholders of DiaManT@Home, a system for Diabetes Management at Home. Stakeholders were identified through the inspection of clinical guidelines [1, 5, 6, 7] which are well known standards for medical care in diabetes.

2.1 The Patient

The principal user of the system. Person who was diagnosed with Diabetes Mellitus.

2.2 Family and close friends

People who lives or have close contact with the patient and is somehow responsible for the patient wellbeing.

2.3 Endocrinologist (Diabetes specialist)

Physician responsible for the overall care of the patient with Diabetes Mellitus disease. This professional is responsible for taking decisions of methods for management and treatment of the diabetes disease and its complications.

2.4 Physician (General practitioner)

Any physician specialist who needs to analyze the overall status of the patient's health conditions. This user includes the endocrinologist.

2.5 Nurse (Diabetes nurse practitioner)

Professional responsible of supporting the disease management of the patient, and assisting physician during the treatment of the disease. Among his/her activities are physical measurement, such as, blood pressure, heart rate, respiration rate, and temperature.

2.6 Nutritionist (Accredited practicing dietitian)

Professional responsible for nutrition of the patient in the daily basis, helping to ensure a healthy life style through a food plan that fits the patient needs.

2.7 Physical Educator/Trainer

Professional responsible for the physical activity of the patient, helping to ensure a healthy life style through an exercise plan that fits the patient needs.

2.8 User

Any of the stakeholders listed above.

3 Functional Requirements

In this section we present the Functional Requirements (FR) of DiaManT@Home, obtained by documents inspection referred in [1, 5, 7].

The management of diabetes mellitus is based on a control of patient glycemic levels and the pursuance of a healthy life style. In order to achieve this goal, the patient must reeducate itself and keep monitoring his/her diet, exercise routine and pharmacological treatments. Considering this scenario, the DiaManT@Home intends to assist the patient to improve his/her condition self-management, as well as, to help all possible interested users of this system, such as the physician, nurses and family to take care of the patient well-being.

Functional requirements are classified in nine categories:

- A. Exercise Monitoring: Requirements that intend to monitor and record data about the physical activities of the patient. It will be mainly used by the patient, the physical educator/trainer and the nurse to collect data and follow the exercise plan established by a professional according to the patient especial needs and limitations.
- B. Nutrition: Requirements that intend to monitor and record data about the diet of the patient. It will be mainly used by the patient, the physician, the nurse, the nutritionist, family and close friends to collect data and follow the nutritional plan established by a professional according to the patient especial needs. It also intends to allow the users to search and include items in a nutritional data base that will be used to, not only store nutritional information of different foods, but also to calculate the percentage of different food groups present at the patient meals. The user will also be able to simulate meals, so he/she will have information about it before the act of eating, helping the user to embrace better food choices.
- C. Pharmacological Treatment: Requirements that intend to monitor and record data about all the medicament that the patient utilizes, including different types of insulin. It will be mainly used by the patient, the physician, the nurse, family and close friends to collect data about every time that the patient uses

any kind of pharmacological substance, helping the patient or the professional responsible for he/she to control the use of medicament, decreasing forgetfulness and avoiding overdose.

- D. Blood Glucose Monitoring: Requirements that intend to monitor the blood glucose level of the patient during his/her daily activities, helping to avoid the occurrence of hypoglycemia or hyperglycemia.
- E. Health Status Monitoring: Requirements that intend to monitor and record data about the general health of the patient, such as weight, high, body measurements, clinical history, exams etc. In this way, building an electronic record of the patient health status.
- F. Activities of daily life monitoring: Requirements that intend to monitor and record data about different daily activities of the patient e.g., alcohol consumption, smoking.
- G. Reminders: Requirements that intend to generate reminders for the patient and other users to don't forget to execute the daily activities, such as exercise, eat, take medicament and do exams.
- H. Alerts: Requirements that intend to generate alerts for the patient and other users about patient abnormal physical measures (e.g., high or low blood glucose levels), or for notify the patient does not make an important action (e.g., when patient forgets to intake a medicament).
- I. Report: Requirements that intend to generate reports containing a resume of daily and weekly events, as well as connecting information (e.g., feeding time and exercise time). This report can be used by all the users to keep track of the patient evolution regarding his/her disease, and to consider improvements or maintenance of his/her treatment.

3.1 List of Functional Requirements

Detailed requirements of each before mentioned category are presented in the remainder of this section.

3.1.1 Exercise Monitoring

- FR1. For each time the patient does some kind of exercise, the system must be able to monitor and record:
- I. The name of the exercise (e.g.: soccer, yoga, running, others, etc.).
 - II. The intensity of the exercise (moderate or vigorous).
 - III. The type of the exercise (aerobic, resistance and/or flexibility).
 - IV. The time the exercise started and ended.
 - V. The amount of time spent exercising.
 - VI. The date.
- FR2. The physician or the physical educator/trainer should be able to include and change an exercise plan for the patient.
- FR3. The patient and the nurse should be able to include and change an exercise plan, which must be approved by a physician or physical educator/trainer.

3.1.2 Nutrition

- FR4. The nutritionist or the physician should be able to include and change a nutritional plan.
- FR5. The patient must be able to register all their meals.
- FR6. The system should have a nutritional data base with different common foods with its respective nutritional data.
- FR7. The patient, the physician, the nurse, the nutritionist, family and close friends should be able to include items in the nutritional data base.
- FR8. The patient, the physician, the nurse, the nutritionist, family and close friends should be able to include custom recipes in the nutritional data base.
- FR9. The system should be able to calculate the nutritional value of recipes based on the nutritional value of the ingredients informed by the user.
- FR10. The system should be able to understand different types of measurement such as weight, relative size (spoon, cup), portion etc.
- FR11. Any user should be able to search for the nutritional information of the foods contained in the data base.
- FR12. The system must monitor and record the amount of water or other liquids the patient is drinking.

FR13. For each meal that the patient has, the system must be able to monitor and record:

- I. The amount of and percentage of:
 - a. Carbohydrates
 - b. Sucrose
 - c. Fructose
 - d. Fibers
 - e. Total fat
 - f. Saturated fatty acids
 - g. Polyunsaturated fatty acids
 - h. Monounsaturated fatty acids
 - i. Cholesterol
 - j. Protein
 - k. Sodium
 - l. Vitamins
 - m. Minerals
- II. The date.
- III. The time that the meal started.
- IV. The time that the meal ended.
- V. The total calories ingested.
- VI. The percentage per food group (carbohydrates, fibers, lipids, proteins, vitamins and minerals, sodium)
- VII. If the patient make use of any type of insulin, and if the treatment is based on carbohydrates counting, the system should calculate the respective amount of insulin necessary for the patient according to the amount carbohydrates ingested and the type of insulin that the patient uses.

FR14. The system should allow the patient, the physician, the nurse, the nutritionist family and close friends to simulate meals before eating, giving the user the following information about the total meal that the user intends to eat:

- I. The amount of and percentage of:
 - a. Carbohydrates

- b. Sucrose
 - c. Fructose
 - d. Fibers
 - e. Total fat
 - f. Saturated fatty acids
 - g. Polyunsaturated fatty acids
 - h. Monounsaturated fatty acids
 - i. Cholesterol
 - j. Protein
 - k. Sodium
 - l. Vitamins
 - m. Minerals
- II. The total calories that will be ingested.
 - III. The percentage per food group (carbohydrates, fibers, lipids, proteins, vitamins and minerals, sodium) contained in the simulated meal.

3.1.3 Pharmacological Treatment

FR15. The system must store any medicament that the patient uses.

FR16. The system must allow the patient, the nurse and the physician to add more medicaments to the system.

FR17. The physician must be able to change data about the medicament.

FR18. For each medicament, the system must store:

- I. Name.
- II. Dosage.
- III. The exactly time the medicament will be used.
- IV. Start date of the treatment.
- V. End date of the treatment.
- VI. Duration of the treatment.
- VII. Administration.
- VIII. Composition.
- IX. Indication.
- X. Side effects and adverse reactions.

- XI. Instructions for overdose.
- XII. Storage Information.
- XIII. Physical characteristics of the medication.
- XIV. Instructions in case the patient forgets to take its medicament.

FR19. For every time the patient uses a medicament, the system must store:

- XV. Name.
- XVI. Dosage.
- XVII. Date and time.
- XVIII. Method of administration.

3.1.4 Blood Glucose Monitoring

FR20. The system must store the glycemic target of the patient, as well as the boundaries for hypoglycemia and hyperglycemia (standard: plasma glucose concentration 80-130mg/dL or 4.4-7.2mmol/L).

FR21. The system must store the Insulin sensitivity of the patient (factor sensitivity) (i.e. how much a unit of ultra-fast insulin lowers your blood glucose in points).

The sensitivity factor is determined by:

$$\frac{1800}{total\ insulin\ dose\ in\ use}$$

for patients using ultrafast insulin analogues and

$$\frac{1500}{total\ insulin\ dose}$$

for those on regular insulin use.

FR22. The system must calculate the correction bolus of the patient given by:

$$Correction\ bolus = \frac{Measured\ blood\ glucose - Glycemic\ target}{Insulin\ sensitivity}$$

FR23. The system must calculate the amount of insulin required by the patient taking into account the carbohydrates counting plus correction bolus and the type of insulin that the patient uses.

FR24. The system must obtain and record the blood glucose level at least:

- I. Before the patient starts any exercise activity.
- II. After the patient ends any exercise activity.

- III. Before any meal.
- IV. 2 hours after any meal.
- V. 3 - 5 hours after any meal.
- VI. Before the patient sleeps.
- VII. Before the patient drives.
- VIII. Before any other critical task.

FR25. The system should obtain and record the blood glucose level as many times as it is possible due to the technology used.

3.1.5 Health Status Monitoring

FR26. The system must be able to obtain and store the weight of the patient.

FR27. The system must be able to obtain and store the size of the patient.

FR28. The system must be able to store the age of the patient.

FR29. The system must be able to obtain and store different measures of the body (ex: circumference of waist)

FR30. The system should be able to store the health record of the patient (past and current diseases, conditions and treatments).

FR31. The system should be able to store the results and date of any exam the patient makes.

FR32. The patient should be able to include data about allergies.

3.1.6 Activities of daily life monitoring

FR33. The system should monitor and record alcohol consumption.

FR34. The system should monitor and record smoking habits.

FR35. The system should monitor and record gastrointestinal disorders (e.g. diarrhea).

FR36. The system should monitor and record the presence of any infections.

FR37. The system should monitor and record the blood pressure.

FR38. The system should monitor and record the heartbeats.

FR39. The system should monitor and record the time that the patient slept and woke up.

3.1.7 Reminders

3.1.7.1 Exercise Reminder

FR40. The system should remind the patient, the nurse, the physical educator/trainer and/or family and close friends of the patient's exercise practice, following the exercise plan.

3.1.7.2 Nutritional Reminder

FR41. The system should remind the patient, the nurse and/or family and close friends of the patient's meal, following the nutritional plan.

FR42. The system should remind the patient, the nurse and/or family and close friends of the patient's water ingestion.

3.1.7.3 Pharmacological Reminder

FR43. The system should remind the patient, the nurse and/or family and close friends of the use of all the medicaments.

FR44. The system should remind the patient, the nurse and/or family and close friends if some pharmacological treatment has its period over.

3.1.7.4 General Reminder

FR45. The system should remind the patient, the nurse and/or family and close friends of the exams listed in Table 1.

Action	Frequency
Height	When stops growing
Blood pressure	12 mthly
Weight	3 mthly
Waist circumference	3 mthly
BMI	12 mthly
BGL	At each visit for client on insulin
Lifestyle modification education	3 mthly

Social emotional support	12 mthly
Foot/amputation check	6 mths; 3 mths if high risk; 2 mths if previous ulcer
Visual acuity	12 mthly
Retinal camera/eye examination	12 mthly
FBC	12 mthly
Liver function test (LFT)	12 mthly
UEC	12 mthly
eGFR	12 mthly; 3 mthly if abnormal
HbA1c	3 mthly
Fasting lipids	12 mthly if stable on hypolipidaemics
Urinalysis	12 mthly
ACR	12 mthly; 3 mthly if abnormal
ECG	12 mthly
Insulin	As per MO/NP
Influenza vaccine	Annually
HW/RN R/V	3 mthly
MO/NP R/V	12 mthly; wkly for active wound
Medication R/V	3 mthly
Diabetes educator	12 mthly
Dietitian	12 mthly
Dentist	6 mthly
High risk foot service team	As required e.g. non-healing foot wound

Podiatrist	12 mthly; 2 mthly if previous ulcer/high risk foot
Physician/ Endocrinologist	On referral by MO/NP

Table 1 - Care plan summary for people with type 2 diabetes retrieved from [7]

FR46. The user should be able to add more reminders of any kind.

FR47. The system should be flexible so the user can modify the frequency of the reminders.

3.1.8 Alerts

FR48. The system should record date, time and a resume in case of occurrence of any alert.

3.1.8.1 Exercise Alert

FR49. The system should give alerts to the patient, the nurse, the physical educator/trainer and/or family and close friends if the patient exceed any boundary established in the exercise plan.

FR50. The system should give alerts to the patient, the nurse, the physical educator/trainer and/or family and close if the patient did not reach achieve any boundary established in the exercise plan.

FR51. The system should alert to the patient, the Nurse, the physical educator/trainer and/or family and close if the patient is not following the exercise plan.

3.1.8.2 Nutritional Alert

FR52. The system should give alerts to the patient, the nurse, the nutritionist and/or family and close if the patient exceed any boundary established in the nutritional plan.

FR53. The system should give alerts to the patient, the nurse, the nutritionist and/or family and close if the patient did not achieve any boundary established in the nutritional plan.

FR54. The system should give alerts to the patient, the nurse and/or family and close if the patient is not drinking enough water.

FR55. The system should alert the patient, the nurse, the nutritionist and/or family and close if the amount of carbohydrate is not being constant.

FR56. The system should alert the patient, the nurse, the nutritionist and/or family and close if the amount of calories ingested was lower/higher than the established in the nutritional plan.

FR57. The system should alert the patient, the nurse, the nutritionist and/or family and close if the amount of any food group was lower/higher than the established in the nutritional plan.

3.1.8.3 Pharmacological Alert

FR58. The system must give alerts to the patient, the nurse and/or family and close if the patient forgot to take any medicament.

FR59. The system must give alerts to the patient, the nurse and/or family and close if the patient make use of any medicament in the wrong dosage, time and/or method of administration.

3.1.8.4 General Alert

FR60. The system must give alerts to the patient, the nurse and/or family and close in case of occurrence of hypoglycemia.

FR61. The system must give alerts to the patient, the nurse and/or family and close in case of occurrence of hyperglycemia.

FR62. The system should give instructions to the patient and the nurse of how to proceed in cases of hypoglycemia.

FR63. The system should give instructions to the patient and the nurse of how to proceed in cases of hyperglycemia.

FR64. The system should alert to the patient, the nurse and/or family and close in case of excess of alcohol consumption.

FR65. The system should alert to the patient, the nurse and/or family and close in case of smoking.

FR66. The system should alert to the patient, the nurse and/or family and close in case of gastrointestinal disorders.

FR67. The system should alert to the patient, the nurse and/or family and close in case of infections.

FR68. The system should alert to the patient, the nurse and/or family and close in case of alterations in blood pressure.

FR69. The system should alert to the patient, the nurse and/or family and close in case of alterations of heartbeat.

3.1.9 Report

3.1.9.1 Exercise Report:

FR70. For each day and each week, the system should be able to give feedback about:

- I. The total amount of time spent for each exercise practiced (e.g.: soccer, yoga, running, others, etc.).
- II. The total amount of time spent for each type of exercise (aerobic, resistance and/or flexibility).
- III. The total amount of time spent for each intensity type (moderate or vigorous).
- IV. The average consumption of carbohydrate before the exercise.
- V. The average consumption of carbohydrate after the exercise.
- VI. The average blood glucose level before the exercise.
- VII. The average blood glucose level after the exercise.
- VIII. The average blood glucose level during the exercise.
- IX. The average ingestion of water or other liquids during the exercise.
- X. The average heart rate for each type of exercise.
- XI. The average heart rate for each intensity of exercise.
- XII. The total number of occurrences of hypoglycemia during or near an exercise practice.
- XIII. The location of injection of insulin near an exercise practice, if there was any.
- XIV. The occurrence of any alcohol consumption, gastrointestinal disorders, smoking or any infectious disease close to the exercise.
- XV. Occurrences of Exercise Alert, including date, time and resume.

3.1.9.2 Nutrition Report:

FR71. For each meal and each day, the system should be able to calculate and report:

- I. The number of meals.
- II. The total calories ingested

- III. The percentage per food group (carbohydrates, fibers, lipids, proteins, vitamins and minerals, sodium)
- IV. Occurrences of Nutritional Alert, including date, time and resume.

3.1.9.3 Pharmacological Report:

FR72. For each day, the system should be able to report:

- I. All medicaments that the patient forgot to take, including:
 - i. Name
 - ii. Dosage.
 - iii. Date and time.
- II. All medicaments that the patient took, including:
 - i. Name.
 - ii. Dosage.
 - iii. Date and time.
 - iv. Method of administration.
 - v. Feedback if the dosage, date, time or method of administration was wrong.
- III. Occurrences of Pharmacological Alert, including date, time and resume.

3.1.9.4 General Report:

FR73. For each day and each week, the system should be able to calculate and report:

- I. The total number of occurrences of hypoglycemia, date and time of each one.
- II. The total number of occurrences of Hyperglycemia, date and time of each one.
- III. Changes in the weight of the patient.
- IV. Changes in the body measures.
- V. Changes in the clinical history, date and time of each one.
- VI. Excess of alcohol consumption.
- VII. Smoking habits.
- VIII. Occurrence of gastrointestinal disorders, date and time of each one.
- IX. Occurrence of any infections, date and time of each one.
- X. Changes in the blood pressure, date and time of each one.

- XI. Changes in the heartbeat, date and time of each one.
- XII. Occurrences of General Alert, including date, time and resume.
- XIII. The time that the patient slept and woke up.

4 Non-Functional Requirements

In this section, the Non-Functional Requirements (NFRs) of DiaManT@Home are presented. The NFRs were defined by a careful selection between more than 150 requirements for quality attributes for Ambient Assisted Living systems established in the quality model QM4AAL [8,9]. The selection was made considering the major needs of people living with diabetes disease at home, i.e., knowledge obtained during the process of developing the functional requirements and the major needs of a HSH System. The list of NFRs is presented in the remainder of this section.

4.1 List of Non-Functional Requirements

4.1.1 Adaptive property: Self-Adaptive

NFR1. The system must provide adaptation to user profiles (e.g., age, health status), preferences (e.g., on body sensor, wristwatch sensor, pedometer integrated into shoes) to the desired information to be processed, in both off and run-time.

NFR2. The system must offer cooperation among constituents, starting both on a user-triggered basis, as well as, as a result of an autonomous decision of the coordinator itself.

4.1.2 Adaptive property: Self-Managing

NFR3. The system must support the deployment of services reducing deployment time and costs.

NFR4. The system must have a simple configuration process, guided by a wizard if appropriate, and carefully designed so as not to be boring or annoyingly long. The configuration process must take explicit advantage of any modern device (e.g., smart-phone, tablet, smart tv, gaming consoles) that users might have.

4.1.3 Adaptive property: Self-Configuring

NFR5. The system must be customizable and reconfigurable at runtime to fit personal user needs in the best way possible.

NFR6. The system must offer the possibility to users to access, configure, and administer relevant parts or properties of deployed services.

NFR7. The system must provide a plug-and-play mechanism for automatic constituent detection. The user should have the possibility to add plug-and-play

systems/components/sub-systems that are automatically detected and integrated in a dynamic way.

NFR8. The system must add new UI components at any time without the need to restart itself.

NFR9. The system must integrate easily new applications.

NFR10. The system must provide discovery and self-configuration mechanisms based on a local database of known device profiles that maintains appropriate data exchange specifications.

NFR11. The system must support configuration of sensors and actuators by a common API and user interfaces.

NFR12. The system must allow for adding new sensors and actuators to the system without rebooting the system.

NFR13. The system must provide services and tools to support the configuration of new software, hardware and services.

NFR14. The system must execute the local configuration process exploiting smart tvs, gaming consoles, and personal computers available in the home, as well as other more pervasive devices like smart-phone and tablet (via suitable apps or ad hoc web sites), as well as via a voice menu system able to guide the user towards the desired configuration in a natural and familiar way.

4.1.4 Adaptive property: Self-Healing

NFR15. The system must be able to adapt not only in case of system shrink. It should automatically allocate resources at runtime to support system functionalities with higher priorities.

NFR16. The system must define measurements for disaster recovery.

NFR17. The system must discover errors and failing components/systems and perform corrective actions, e.g., restart failing or erroneous components/systems.

4.1.5 Adaptive property: Self-Protecting

NFR18. The system must avoid the failures propagation to other components/ systems.

NFR19. The system must provide protection mechanisms within the architecture to handle software errors.

NFR20. Each system constituent must detect data modifications and prevent unauthorized modifications. This applies specifically to service user data, sensor

data and commands sent to actuators, but could also apply to some extent to private communications between end-users.

4.1.6 Adaptive property: Situation-aware

NFR21.The system must have a diagnostic service that must have a holistic view of the system, so that correlated failures and anomalies can be detected.

4.1.7 Adaptive property: Context-aware

NFR22.The system must provide means for resolving conflicting context information coming from different context sources.

NFR23.The system must have user interfaces capable to provide short and understandable feedback to the user. Whenever possible, actions performed by user shall be reversible.

4.1.8 Accessibility requirements

NFR24.Systems must offer accessible and easy to use user interfaces for elders, so they can easily understand when there is a risky situation.

NFR25.The system must be easy to set up the personal profile of patients.

NFR26.The system UI must be fully accessible. The system must offer their services to people with severely impaired eye-sight, cognitive level of functioning, or middle cognitive impairment elders.

4.1.9 Adaptability requirements

NFR27.The system must employ an adaptable, wearable gateway device to harvest data from a variety of holters, wearables and biosensors.

NFR28.The system must define a comfortable way to adapt it to wide variety of different end user needs.

4.1.10 Adaptivity requirements

NFR29.The system user interface must incorporate features for coping with access impairments and capability changes due to ageing.

4.1.11 Authenticity requirements

NFR30.The system constituents must identify and authenticate an entity (i.e., human users and other systems or components) that wants to use them.

NFR31.The system must authenticate and authorize entities in the multi-user settings.

NFR32.The system must certify each constituent system individually.

4.1.12 Confidentiality requirements

NFR33. System constituents must protect data storage or communication to ensure confidentiality and integrity of this data.

NFR34. The system must have reliable means for authentication, secure transmission method, secure server environment and application, and deployment of security policies covering, e.g., management and maintenance processes.

4.1.13 Dependability requirements

NFR35. The system must support the delivery of services that can justifiably be trusted, where the service is the intended behavior of the system. The system must be resilient with respect to unanticipated behavior from the environment or of constituents (e.g., transient and permanent hardware faults, design faults).

4.1.14 Deployability requirements

NFR36. The system must define protocol and infrastructure for easy deployment of services.

4.1.15 Easy interaction requirements

NFR37. The system must support multi-modal user interaction.

4.1.16 Efficiency requirements

NFR38. Data structures used for storing data in the system must be efficiently designed in the context of representation and serialization.

4.1.17 Fault-tolerance requirements

NFR39. The system architecture must provide an error-detection mechanism to distinguish between transient and permanent faults.

4.1.18 Flexibility requirements

NFR40. The system must offer language configuration, intended as the set of commands usable to control the configuration process, linguistically expressive and efficient.

NFR41. The system must support both local access exploiting available appliances such as smart TVs, wall screens, touch screens, gaming consoles, voice systems – and remote access - via text messages, short messages, voice messages, apps, wizards, web sites, etc.

4.1.19 Freedom for risk requirements

NFR42.The system must offer reliable data to base diagnosis and health decisions.

4.1.20 Integration requirements

NFR43.The system must facilitate the communication and integration of arbitrary numbers of sensors, actuators, control units, appliances, and application/systems into the system, independently of communication protocols.

4.1.21 Interoperability requirements

NFR44.The system must use common vocabularies covering both clinical and non-clinical contents in order to achieve semantic and syntactical interoperability.

NFR45.The system must allow external interoperability, this is, it must integrate external and legacy services/systems and modules

NFR46.The system must support the timely and time-dependent combination of data-streams that originate from existing different devices.

4.1.22 Maintainability requirements

NFR47.The system must provide services and tools to support the installation of new software, hardware and service into the system and to install precompiled software modules

NFR48.the system design must be highly modular and extensible for facilitating maintenance and administration.

NFR49.The system must allow a technical support personnel to the users easily maintain the system after the deployment (i.e., to monitor state of the system, to identify exceptions or faults).

NFR50.The system must offer ease maintenance through identification of faulty systems.

4.1.23 Non-repudiation requirements

NFR51.The system must to trace back actions on sensitive assets to the human or system component that was responsible for this action.

4.1.24 Privacy requirements

NFR52.the system must guarantee its secure operation and prevent the abuse of person-related information.

NFR53.The system must protect user's private data and respect the user's privacy, in order user feels assured.

NFR54.The system must protect sensitive health information to avoid that patient's information be used for other purposes (e.g., to publish in social networks the health status of the patient). Unauthorized access to health information must be prevented.

4.1.25 Reliability requirements

NFR55.The system and its constituents must manage personal and health-related information in a reliable way.

NFR56.The system must be highly reliable to address the distinct and measurable impact of possible failure.

NFR57.The system must offer mechanisms to ensure a proper execution of components/constituents and application.

NFR58.The system communication infrastructure must provide prioritization of messages to ensure transfer of emergency related messages.

NFR59.The system must provide reliable authentication to improve the confidentiality of the handled health-related information.

4.1.26 Security requirements

NFR60.The system must implement access control mechanisms for collected data (e.g., by employing fingerprint authentication for the user).

NFR61.The system must provide trust between the communication services by establishing agreements between the PHR (Personal Health Recorders) service providers and the system must protect the user interface of services due to users have full control on the PHR information.

4.1.27 Trust requirements

NFR62.The system must ensure trust to the data measured by patients or consumers that will be used by professionals to monitor the health-status of patients.

NFR63.The system must be trustworthy and thus protect personal information.

5 Relationship between functional and non-functional requirements of DiaManT@Home.

In this section, we present relationships for all Non-functional Requirements (NFRs) previously selected with the intention of justify the choice of each one of them, as depicted in Table 3. The first column lists all the NFRs. The second column presents other NFRs that are directly correlated to the respective NFR. The third column presents the Functional Requirements (FR) that are related to the NFR. Columns 4, 5 and 6 labels the NFR according to priorities for the design of the software architecture for DiaManT@Home. Specifically, Column 4 and 5 represent the priority level given by two different reviewers. Column 6 represents the final decision regarding priority level of each NFR, after conflict resolution session between both reviewers.

During the labeling process were used five different priority levels, as presented in Table 2: (i) NFRs that were considered essential for the proper functioning of the system (obligatory in red color), (ii) requirements that are strongly desired (desired with priority in orange color), (iii) desired requirements (desired in yellow color), (iv) requirements that are desirable but not fundamental for the purpose of the system (desired but not essential in light green color), and (v) NFRs which are considered optional and may or may not be part of the project scope (optional in dark green color).

Finally, the last column in Table 3 gives us additional information about the NFR that may be important for its comprehension.

Priority levels label	Color
Obligatory	Red
Desired with priority	Orange
Desired	Yellow
Desired but not essential	Light Green
Optional	Dark Green

Table 2 – Reference for priority levels label.

Non-functional Requirement Number	Related Non-functional Requirements Numbers	Related Functional Requirements Numbers	Priority Levels - 1° Revision	Priority Levels - 2° Revision	Priority Levels - Final Revision	Additional Comments
NFR1						The system must be designed for different stakeholders, hence the need of adaptation to different user profiles is clear.
NFR2		FR1-5, FR12, FR13, FR15-73				The constituents named in the Functional Requirements Documents must offer cooperation both in the communication between the Pharmacological Treatment, Nutrition and Blood Glucose Monitoring for the correct calculation of insulin injection as well as the generation of Alerts, Reminders and Reports.
NFR3	NFR4					The system must make as simple as possible to deploy new services, reducing the effort of the user to use the system.
NFR4	NFR1, NFR3					The system must be easy to use for all types of users and easy to configure for all types of configuration of different profiles.
NFR5	NFR1, NFR8, NFR12					The system must be efficient and easy to use, hence should respond to actions during runtime.
NFR6		FR2, FR3, FR4, FR46, FR47				Administrative tasks (configuration, CRUD)
NFR7	NFR3, NFR9					The system should be capable to support different constituents

						and to facilitate the user operation of the system, it should detect the constituents by itself.
NFR8	NFR5, NFR12					Run-time integration.
NFR9	NFR3, NFR7					
NFR10	NFR3, NFR7, NFR9					Interoperability of data between devices.
NFR11	NFR3-6, NFR13, NFR14					
NFR12	NFR5, NFR8					Run-time integration.
NFR13	NFR3-6, NFR11, NFR14					
NFR14	NFR3-6, NFR13, NFR13					
NFR15	NFR16, NFR17	FR20-25, FR40-69				The system must be Self-Healing so that the possible errors do not affect the user well-being.
NFR16	NFR15, NFR17					
NFR17	NFR15, NFR16					
NFR18	NFR2, NFR15-17					The system must be uncoupled so that failures do not propagate to other components.
NFR19	NFR15-17					
NFR20	NFR18	FR1-5, FR7, 8, FR12, FR13, FR16, FR17, FR19, FR20, FR24-39				The system must prevent data incompatibility for any recorded data.
NFR21	NFR2, NFR15-20					
NFR22	NFR21	FR1-5, FR7, FR8, FR11-13, FR16,				The system must be aware of the different data sources that

		FR17, FR19, FR20, FR24-39				the user might be using.
NFR23	NFR4	FR1-5, FR7, FR8, FR11-13, FR16, FR17, FR19, FR20, FR24-39				The system must be easy to use and communicate well with the user every time he/she does some action regarding the system.
NFR24	NFR1, NFR23	FR1-5, FR7, FR8, FR11-14, FR16, FR17, FR19, FR20, FR24-73				Once Diabetes is a life-time disease, it must be easy to use for elders.
NFR25	NFR1, NFR24					
NFR26	NFR1, NFR24					The system must be prepared for complications of the disease as well as common ageing difficulty.
NFR27	NFR20, NFR22	FR1, FR12, FR13, FR17, FR19, FR20, FR24-39				The system must be prepared to handle a variety of data sources.
NFR28	NFR1					
NFR29	NFR1, NFR23, NFR24, NFR26					
NFR30						The system must be secure and verify the authenticity of entities.
NFR31	NFR1					The system must be secure and verify all users.
NFR32	NFR2					The system must be uncoupled and verify the each constituent system individually
NFR33	NFR2, FR19-22	FR1-5, FR7, FR8, FR11-13, FR16, FR17, FR19,				

		FR20, FR24-39				
NFR34	NFR30-33					
NFR35	NFR15-20, NFR30-32					
NFR36	NFR3, NFR4, NFR6, NFR10, NFR13					
NFR37	NFR1					
NFR38		FR1-8, FR11-13, FR15-39				
NFR39	NFR15-20					
NFR40						The system should be flexible to adapt to different user's preferences.
NFR41						
NFR42	NFR15-20, FR30-32	FR1-5, FR15-19, FR20-25				The system must be secure and ensure reliable information, such as glucose level, medicament doses etc.
NFR43	NFR21, NFR22	FR1-5, FR7, FR8, FR11-13, FR16, FR17, FR19, FR20, FR24-39				The system must handle different sources of data and the integration between them.
NFR44	NFR1, NFR23-26					The system must cover different types of users.
NFR45	NFR21, NFR22, NFR43					
NFR46	NFR21, NFR22, NFR43					
NFR47	NFR3-6, NFR11, NFR13, NFR14					
NFR48	NFR2, NFR32					The system must be

						maintainable, hence it must be modular and easy to identify faults.
NFR49	NFR1, NFR15- NFR17, 21					The system must be maintainable, hence it must be modular and easy to identify faults.
NFR50	NFR15-20 , NFR39					
NFR51		FR1-5, FR7, FR8, FR11- 13, FR16, FR17, FR19, FR20, FR24- 73				The System must trace back actions to ensure reliable data and maintain a log of activities.
NFR52	NFR33, NFR34, NF53	FR1-5, FR7, FR8, FR11- 13, FR15, FR16, FR19- 39, FR70-73				
NFR53	NFR33, NFR34, NFR52	FR1-5, FR7, FR8, FR11- 13, FR15, FR16, FR19- 39, FR70-73				
NFR54	NFR30, NFR31, NFR33, NFR34, NFR52, NFR53	FR1-5, FR7, FR8, FR11- 13, FR15, FR16, FR19- 39, FR70-73				All collected data must be protected from being changed or accessed by outsiders.
NFR55	NFR1, NFR54	FR1-5, FR7, FR8, FR11- 13, FR15, FR16, FR19- 39, FR70-73				
NFR56	NFR15-21, NFR39					
NFR57	NFR15-21, NFR39					The system must ensure that all components/constituents of the system works and handle any possible faulty.

NFR58	NFR33	FR40-69				Alert and Reminders messages.
NFR59	NFR30-32, NFR52-54					
NFR60	NFR30- NFR32, NFR52-54, NFR59	FR1-5, FR7, FR8, FR11- 13, FR16, FR17, FR19, FR20, FR24- 73				
NFR61						Service and infrastructure used by the system must be certified by normative organizations in healthcare area such as ISO or Continua
NFR62	NFR42, NFR51	FR1-5, FR7, FR8, FR12, FR13, FR16- FR39				The system must be secure and use trustworthy data.
NFR63	NFR15-21, NFR39, NFR42, NFR56, NFR57	FR1-5, FR15- 19, FR20-25				

Table 3 - Relation table for all Non-functional Requirements

6 Final Remarks

The effort of establishing the requirements of a system is rather a complex task, once it involves a deep knowledge of the topic to be represented and the main problems that DiaManT@Home must solve. For this reason, the functional and non-functional requirements presented in this document, when identifying the characteristics of the system that is being developed, ensure that most of the main requirements needed to the patient's well-being and correct management of the condition in their homes will be present in the final scope.

A consistent job of requirements analysis ensures a consistent and quality system, once it will be used for selection criteria in future design choices, assisting in the future implementation of the system's functionalities. Furthermore, it reduces future mistakes that can be presented in next stages of software development.

The knowledge contained in the Reference Architecture for HSH systems presented in [4,10], as well as the Quality Model for AAL systems - QM4AAL- presented in [8,9] were very helpful in the establishment of both functional and non-functional requirements of DiaManT@Home, a system to support Diabetes Management at Home. Particularly, the QM4AAL was effective in reducing time and effort for selecting the NFRs, while still guaranteeing quality for the final system. At the same time, this document provided evidence about the applicability of the knowledge contained in such reference architecture.

As future work, we intend to design the software architecture of DiaManT@Home, which involves choosing a pre-existing architectural pattern/style that better fits in this requirements document and then, choosing the architectural views that are more suitable for the HSH system, based on the Reference Architecture for HSH systems [4]. To conclude, a validation of the software architecture will be conducted using the scenario-based technique.

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