NESTORE Platform Requirements

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Short Abstract

This documents aims at investigating, analyzing and describing the requirements for NESTORE platform, deriving from the monitoring requirements defined in WP2 and the related sensors and ecosystem.

The requirements definition also integrates the analysis of the stakeholders' desiderata gathered in WP2 and involved ICT developers, in order to understand which (or how to compute/extract) variables, features and technologies are needed to build the personalized monitoring and interactive coaching system that the NESTORE platform should develop and implement.

Ideal functional requirements are defined by WP2 taking into account the ageing process, while WP7 contribute with the user's point of view and refine requirements according to a co-design methodology. In this deliverable, requirements are prioritized and a set of technical features are derived accordingly.

This document also aims at reporting the NESTORE requirements from the point of view of data, specifically in relation to security and privacy issues. In it, we faced data security describing problems and solution in order to ensure sensible data safety and confidentiality. Furthermore, the last part of this deliverable is an overview of privacy problem with a description of the requirements for the new EU General Data Protection Regulation, entering into force in the coming may 2018.

This document is the input to other WP6 tasks for the definition of architecture, communication interfaces and integration. Deliverable D6.2 and D6.3 will validate these requirements and will define how these specifications would be developed and implemented into the NESTORE platform.

The following chapters will describe the requirements from two different points of view: functional requirements and non-functional requirements. Functional requirements are all the features, directly related to the users, and which are composed of the monitoring system, the decision support system and the virtual coach. The non-functional requirements are strictly related to platform acceptability and reliability and consists of usability, wearability, security and privacy requirements.

Key Words

NESTORE Variables, Data, Platform requirements, Privacy, Security, GDPR.

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1 NESTORE Platform Requirements Overview

1.1

1.1 Introduction

NESTORE is a multidomain, multiparameter, modular platform. These characteristics introduce an intrinsic complexity on the system.
Complexity is deriving from the discrepancy between experts' requests and users' compliance to technology and procedures: we need to take into consideration both experts and users' needs which can sometimes be discordant and, non-rarely, the opposite. Complexity is deriving from the required multidisciplinary technological approach which needs to be tailored with the features mentioned before. Complexity is deriving from the data processing algorithms and the data protection solution to be designed and adopted accordingly.
In order to provide the best description for all the NESTORE platform requirements, starting form D2.1 and D7.1, a questionnaire was submitted to NESTORE experts (both technological and not). The questionnaire (see Annex 1) is divided into three parts;

- the first part is for ICT experts and includes the technological aspects and features for the platform to be designed for the shared and agreed NESTORE general goals;
- the second part is for experts who are in contact and work with users and includes specific questions about users' relationship with technology (e.g. own Internet access, smartphone, computer…);
- the third part is for general experts and asks how data should be managed and used.

These different fields to which the experts belong, also reflects the separation of NESTORE requirements into two different categories: functional requirements and non-functional requirements.

1.1.1 User requirements

As described in Deliverable 7.1, co-design is a methodology which allows to different actors to be part of the development since the first steps. Some methodology, like the one described in D7.1 (Exibition in a Box) enable users to be engaged in the development of the app and express their needs without a great deal of technical knowledge. Requirements for a platform based in ICT tecnology specify what users want or desire form the system. The table below lists the user requirements that should be considered in the development and implementation of NESTORE. The findings are drawn from the user-centred older expert workshops reported in T.1 and T.3 and align with findings and guidelines that emerged from the the Personal User Experience (PUX) working group of the European Innovation Partnership on Active and Healthy Ageing (EIPonAHA) https://gpii.eu/pux/guidelines/PUX-Recommendations.V1.pdf

The list below are features that should be considered and aim to be embedded in the design and functionality of NESTORE to maximise it acceptance and uptake amongst users.

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Trust	Privacy/security/ reliability of NESTORE
	The system's management of data is transparent. Users are aware of where data goes and how it is used. The user has control over their privacy settings (in a usable manner and who has access to the data)
	Health-related data is accurate and has the option to be viewed in real-time by users of the system (which might be more appropriate for certain health conditions)
	Users have the capacity to turn off analytics (on/off switch)
	The system will translate health-data into contextualised user-centred feedback appropriate to its audience
	The system should be robust and withstand everyday use
	The system should not compromise or effect other health-technologies of the user (e.g. pace-maker)
	Charging (power) requirements should not interfere with lifestyle
	Software updates should not alienate access.
Cost	Affordability
	NESTORE should be scalable (e.g. inclusive core features with option to purchase/add additional functionality)
	Costs should not be prohibitive to the specified user group
Fits my life	NESTORE must be user-centred and responsive to reflect the needs and preferences of the end user including considerations of ergonomics
	Interface should be clear, concise and visually appropriate with the opportunity for manual customisation by the user reflecting their own preferences and style
	The visual interface (e.g. Icons) should be easily recognisable, provide consistent look and feel
	Single sign in (log in once rather than multiple times)
	The system should provide a creative user-friendly solution for log in and resource access
	Users settings should be remembered throughout the platform
	When the user changes the interface settings the interface should be updated immediately and continuously

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	Resource/functions should be accessible and usable by all users of the system. Features should include interaction modes for touch and voice alongside high visibility settings appropriate to personal needs (e.g. high contrast for people with visual impairment etc.) and language settings/options Language should be clear and meet the needs of individuals with varied literacy skills
	The system should be responsive and adapt itself to the environment and user needs
	The system should have the capacity to be used beyond the user's physical home environment

Table 1: User needs

1.1.2 Functional Requirements

The first category of requirements are mandatory and strongly linked with the platform functioning, and at the same time, they give shape and influence the structure of the platform itself and describe how the system works, how it is perceived by the users and how it interacts with them. We call them functional requirements.
Functional requirements are closely related to NESTORE domains which are the following ones:

- User's attitude to use of technology
- Monitoring System
- Decision Support System
- Virtual Coach
- Serious Game

1.1.3 Non-functional Requirements

Instead, non-functional requirements are those features which are considered not related to specific functions of the platform, but which are essential in terms of its accuracy, reliability and usability.
The absence of those features does not compromise how the system works but influence its efficacy and reliability in sensing and delivering coaching solutions, are related to how the users perceive and related with the NESTORE system, and how much users are confident and encouraged to use the NESTORE platform and feel safe using it.
The considered non-functional requirements are:

- Security
- Privacy
- Wearability and Usability

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2 Functional Requirements

Functional requirements are all the features and aspects directly connected to the use of the platform. In the previous paragraph, seven main requirement groups have been presented as closely related to the domains and subdomains described in the DoA and also reported in D2.1.
These functional requirements groups could be split into three main categories which corresponds also to the development structure of NESTORE platform:

- Monitoring system
- DSS – Decision Support System
- Virtual Coach

These three main categories have been chosen in order to help experts in implementing the NESTORE architecture.
Moreover, paragraph 2.4 identifies the environmental features which are needed for the proper functioning of the system and which have been highlighted by the experts.

2.1 Monitoring system

Monitoring system is the fundamental part through which NESTORE platform measures and analyzes the user status behaviour with the aim of creating a customized behavioral model and virtual coach able to give personalized suggestions. This should ensure the best system efficacy at single user level.

NESTORE monitoring system is related to wearable devices and environmental sensors. Wearable could be an excellent solution for acquiring heath related and lifestyle data (e.g. Cardio-Respiratory and movement data), but some data are needed to be acquired by means of other input systems. This could be done with questionnaires implemented into mobile App rather than environmental sensors.

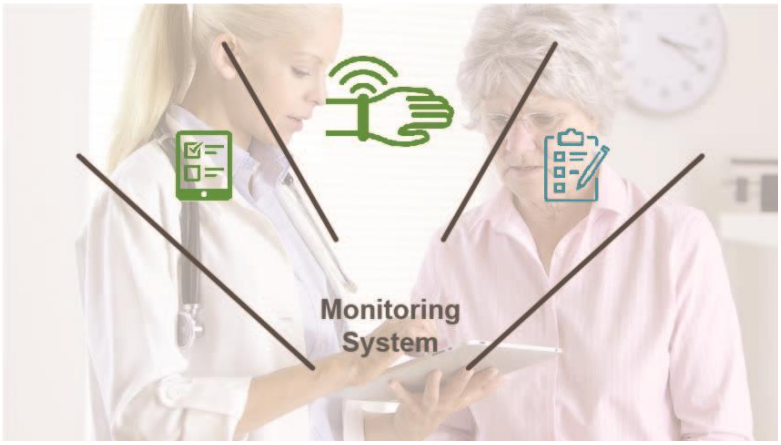

Figure 1: Monitoring system inputs

From the D2.1 and users inputs D7.1 a set of tables summarizing all the variables (including description, data collection method and data collection technology, priority and notes) has been prepared and shared among experts and partners to agree on the definition of the Platform Requirements.
These tables take into account all the variables of interest for the NESTORE platform highlighted by WP2 and analyze them with the aim to understand how they can be measured and interpreted, together with the importance for the NESTORE system for assessment of for coaching strategies definition/implementation.

In the next pages the three tables, one for each NESTORE domain, are reported.

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2.1.1 Physiological status & Physical Activity

The physiological status and physical activity variables analysis has been divided into the following categories:

- Anthropometric characteristics
- Cardio-respiratory Function
- Motor Function
- Sleep Quality

in order to help reading the numerous variables.

Table 2 report the name of the variable, the measurement unit (where possible), the physical or physiological measurement methods and if a device can be already found on the market or needs to be developed (both for wearable and environmental sensors). The table continues reporting which kind of devices can be used the measure the variable and the usage priority reported by NESTORE expert in the WP2. The last column describes the sampling frequency to be adopted by the sensor or the user to comply with the DDS and coaching system.

In Table 2, Table 3 and Table 4, the following legend and classification are adopted:
* COTS - Commercial Off-The-Shelf component: this column describes if a wearable, environmental or general device is already available on the market.
**Werable and Environmental – These columns indicate if a device is already in the market (COTS) or need to be developed in order to acquire the data in the row.
*** classification of Priority for NESTORE platform: 1. Mandatory, 2. Important, 3. Optional, 0. to be excluded
AU: Arbitrary Unit

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Variable name	Measurement Unit	Measurement Methods	COTS* Device	TYPE of device	Wearable**	Environmental**	Priority for NESTORE Platform***	Data measurement frequency
Anthropometric characteristics								
Body height	cm	meter	YES	Analog or digital meter Smart mirror Smart camera/Kinect		DEV: Smart mirror and camera could be implemented	1	Only the first time
Body weight	kg	scale	YES	Analog or smart scale Sensorized carpet Wii + balance board		DEV: Sensorized carpet and Wii data gathering could be implemented	1	Once a week
Body Mass Index BMI	kg/m^2	computed		Computed from other variables	-	-	1	Once every 4 weeks
Fat Mass	Kg or %	Plicometer, Bioimpedance, body circumferences, other invasive methods	YES	Analog or digital Plicometer Analog or digital Meter Smart scale	-	COTS	1	Once every 4 weeks
Fat-free Mass	Kg or %	Plicometer, Bioimpedance, body circumferences, other invasive methods	YES	Analog or digital Plicometer Analog or digital Meter Smart scale	-	COTS	0	
Skeletal Muscle Mass	Kg or %	Plicometer, Bioimpedance, body circumferences, other invasive methods	YES	Analog or digital Plicometer Analog or digital Meter Smart scale	-	-	3	Once every 4 weeks
Hip circumference	cm	Meter, strain gauge	YES	Analog or digital meter, wearable strain gauge	DEV	-	1	Once every 4 weeks

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Waist circumference	cm	Meter, strain gauge	YES	Analog or digital meter, wearable strain gauge	DEV	-	1	Once every 4 weeks
Waist-to-height ratio	%	computed		Computed from other variables	-	-	1	
Waist-to-hip ratio	%	computed		Computed from other variables	-	-	1	
Cardio-respiratory Function								
Blood pressure	mmHg	sphygmomanometer, oscillometric method	YES	Analog or digital (wireless connected) sphygmomanometer, smart bracelet	DEV: Oscillometric method could be implemented but needs validation		1	Once a week
Cardiac output	l/min	bioimpedance other invasive methods	YES	Bioimpedance analysis	DEV: Bioimpedance wearable device could be implemented		0	
Heart rate	bpm	Electrocardiogram, Capacitive electrodes electrocardiogram, ballistocardiogram	YES	HR monitor, Electrocardiograph	COTS: Many Bluetooth HR monitors on the market; DEV: Ad-hoc device could be implemented	DEV: Environmental ballistocardiogram could be implemented	1	Once a week
Heart rate variability	Bpm	Computed		Computed from ECG			1	Once a week
Stroke volume	ml	bioimpedance other invasive methods	YES	Bioimpedance analysis	DEV: Bioimpedance wearable device could be implemented		0	

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Dynamic lung volumes	l	spirometry	YES	Spirometer (wireless connected)			0	
Oxygen saturation	%	Reflectance or transmission pulse-oximetry	YES	SPO2 pulse oximetry	DEV: ad-hoc wearable solution could be implemented		1	Once every 2 weeks
Respiratory muscle performance	%	Invasive methods (non-invasive methods are inaccurate)	YES	Invasive methods			0	
Breath frequency	Breath/min	Bioimpedance Chest movement, ECG derived breathing	YES	Bioimpedance Inertial measurement unit (IMU) Camera, Algorithm	COTS: Device only for women DEV: wearable device could be implemented for optimization	DEV: solution with cameras could be implemented	3	Once every 2 weeks
Pulmonary ventilation	l/min	spirometry	YES	Cycloergometer Spirometer			0	
Static lung volumes	l	Invasive spirometry	YES	Spirometer with helium gas			0	
Aerobic fitness – Maximum VO_2	l/min	Spirometry or calculated	YES	Metabolic system or calculated			3	Once every 4 weeks
Anaerobic threshold	l/min	Invasive measurement	YES	Invasive measurement (lactate)			0	
Cardiovascular fitness		Computed		Computed			0	
Cardiac output vs exercise intensity slope ($CO\text{-}VO_2$)		Computed		Computed			0	

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Exercise Heart Rate	Bpm	Electrocardiogram	YES	HR monitor, Electrocardiograph	COTS: Many Bluetooth HR monitor on the market; DEV: Ad-hoc device could be implemented:	DEV: Ballistocardiogram during exercise is very hard to implement	1	Every day
HR Reserve	% or bpm	computed		computed			2	
Habitual Walking speed	m/sec	Accelerometer, cameras	YES	Inertial Measurement Unit, camera	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	2	
Maximal Cardiac Output	L/min	bioimpedance other invasive methods	YES	Bioimpedance analysis	DEV: Bioimpedance wearable device could be implemented		0	
Maximal and Peak Heart Rate	Bpm	Electrocardiogram	YES	HR monitor, Electrocardiograph	COTS: Many Bluetooth HR monitor on the market; DEV: Ad-hoc device could be implemented:	DEV: Ballistocardiogram during exercise is very hard to implement	2	Once every 4 weeks
Maximal Pulmonary Ventilation	L/min	spirometry	YES	Cyclo-ergometer Spirometer			3	

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Post-Exercise Heart Rate Recovery	Bpm	Electrocardiogram	YES	HR monitor, Electrocardiograph	COTS: Many Bluetooth HR monitor on the market; DEV: Ad-hoc device could be implemented:	DEV: Ballistocardiogram could be implemented	2	
Target Heart Rate	Bpm	Electrocardiogram	YES	HR monitor, Electrocardiograph	COTS: Many Bluetooth HR monitor on the market; DEV: Ad-hoc device could be implemented:	DEV: Ballistocardiogram could be implemented	1	
VO_2 Reserve	%	computed	YES	computed			0	
VO_2 Rest	L/min	spirometry	YES	Cyclo-ergometer Spirometer			0	
Motor Function								
Muscle cross sectional area	cm^2	meter	YES	Analog or digital meter			0	
Muscle physiological cross-sectional area	cm^2	meter	YES	Analog or digital meter			0	
Muscle mass	Kg or %	Plicometer, Bioimpedance, body circumferences, other invasive methods	YES	Analog or digital Plicometer Analog or digital Meter Smart scale			3	Once every 4 weeks
Muscle thickness	mm	Invasive methods	YES	Invasive methods			0	
Pennation angle	Degree	Invasive methods	YES	Invasive methods			0	

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Range of movement	Degree or rad	Inertial sensors Camera	YES	More inertial sensors, camera, Kinect	COTS: Some solution for full-body motion tracking are already available on the market DEVS: Could be implemented with multiple sensors		1	Once every 4 weeks
Balance	cm	Balance test with accelerometer, or camera.	YES	inertial sensors, camera, Kinect, Wii + Balance board	DEV: Wearable solution could be implemented	DEV: Solution based on camera can be implemented	1	Once every 4 weeks
Clinical Anaerobic Fitness	W or W/kg	Power generated in short exercise	YES	Cyclo-ergometer			0	
Flexibility		Accelerometer	YES	Inertial sensors, cameras, Kinect, Wii + balance board	DEV: Wearable solution could be implemented	DEV: Solution based on camera can be implemented	2	Once every 4 weeks
Muscle Power	W or W/kg	Different sensors on object and on body		Pressure sensors, force sensors…	DEV: Wearable solution could be implemented	DEV: Sensors on object could be implemented	1	Once every two weeks
Muscle Strength	Kg, N, Nm	Different sensors on object		Pressure sensors, force sensors…		DEV: Sensors on object could be implemented	1	Once every two weeks
Movement Speed	m/s	GPS, accelerometer, camera	YES	GPS, Inertial sensors, cameras	COTS: Some solution for full-body motion tracking are already available on the market DEVS: Could be implemented with multiple sensors	DEV: Sensors on object could be implemented	3	Once every week

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Distance	m	GPS, accelerometer, camera	YES	GPS, Inertial sensors, cameras	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	1	Every day
Exercise Duration	Sec, min	accelerometer, camera	YES	Inertial sensors, cameras, Kinect,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	3	Every day
Exercise Intensity	-	computed	YES	Computed from HR, inertial sensors, Kinect			3	Every day
Exercise Type	-	Inertial sensor, camera		Inertial sensor/s, camera, Kinect	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	3	Every day
Exercise Frequency	-	Inertial sensor, camera		Inertial sensor/s, camera, Kinect	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented.	3	Every week
Fatigue Accumulation	-	Invasive method	YES	Invasive method (lactate)			0	

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Grade (inclination during walking and running)	Degree or rad	Inertial sensor, camera		Inertial sensor/s, camera	COTS: Some solution for fullbody motion traking are already available on the market DEVS: Could be implemented with multiple sensors	DEV: solution with cameras could be implemented	2	
Physical Activity Level	AU	Inertial sensor, camera		Inertial sensor/s, camera	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	1	Once a week
Rate of Perceived Exertion	AU	BORG scale	YES	Questionnaire			3	
Sedentariness	s/min	Inertial sensor, camera	YES	Inertial sensor/s, camera	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	1	Once a week
Speed	m/s	Inertial sensor, camera	YES	Inertial sensor/s, camera	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	2	

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Steps	No. of steps	Inertial sensor, camera	YES	Inertial sensor/s, camera	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras could be implemented	1	Every day
Upper Limb Movements	No. of movements	Inertial sensor, camera	DEV	Inertial sensors, camera, kinect	COTS: Some solution for full-body motion tracking are already available on the market DEVS: Could be implemented with multiple sensors	DEV: solution with cameras could be implemented	3	
Sleep Quality								
Perceived Calm Sleep	Index 1 to 5	Inertial sensor, camera, questionnaire	YES	Inertial sensors, camera, analog or digital questionnaire	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	1	Every day
Sleep Efficiency	%	Calculated	YES	Calculates from total sleep time and Time in Bed	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	1	Every day

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Total Sleep Time	min	Inertial sensor, camera	YES	Inertial sensors, camera,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	1	Every day
Sleep Onset	min	Inertial sensor, camera	YES	Inertial sensors, camera,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	2	
Sleep Offset	min	Inertial sensor, camera	YES	Inertial sensors, camera,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	2	
Time in Bed	min	Inertial sensor, camera	YES	Inertial sensors, camera,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	2	

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Awakening	No. of awakenings, duration (min)	Inertial sensor, camera	YES	Inertial sensors, camera,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	2	
Sleep onset Latency	min	Inertial sensor, camera, Electroencephalogram	YES	Inertial sensors, camera,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	1	Every day
Wake after sleep onset	min	Inertial sensor, camera	YES	Inertial sensors, camera,	COTS: Many Bluetooth activity tracker on the market; DEV: Ad-hoc device could be implemented:	DEV: solution with cameras and sensors in/under bed could be implemented	1	Every day

Table 2: Physiological Status and Physical Activity variables

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2.1.2 Nutrition

Nutrition, as well as Physical Activity, is the domain on which aging has more impact. Ageing came often with physiological changes which can impact on nutritional status. A decreased sense of taste or smell, dental or gastric problems or also the progressive loss of vision and hearing can impact significantly on diet. Moreover, ageing may also be associated with psychosocial and environmental change which can bring elderly to isolation, loneliness and depression which can dramatically influence diet and nutrition.
Monitoring nutrition is mandatory in order to control the status of users and suggest, by means of coach, proper diet or exercise.
The following Table 3, as in the chapter above, reports variables which can be useful for nutrition monitoring and explains how they can be measured or computed by means of electronic, wearable or environmental devices.

2.1.3 Cognitive and Mental status & Social Behaviour

Cognitive decline is often related with old age; this decline can cause cognitive impairment due to loss in cognition, memory, attention apart from processing capability. This cognitive decrease can evolve in loneliness due to fear to being judged; the lack of social interaction can lead to a general worsening of cognitive and mental state. On the other hand, large numbers of adults on seniority threshold are not demented but they need continuous attention and exercised in order to maintain their mental status.

Table 4 report the mainly variables which can be used for Cognitive and Social behaviour monitoring, reporting how they can be measured.

2.2 Decision Support System

2.2.1 Functionality description

The Decision Support System (DSS) is a software that can be considered the intelligence of the Nestore System. DSS processes data in order to take decisions in complex situations due to large number of indicators expected to be measured. In **Error! Reference source not found.**, it is depicted the main subcomponents of the DSS and the relations among them.

The various sensors and applications deployed in the NESTORE platform, generate the input data of the DSS. The data is sent to the NESTORE cloud by other modules of the system. As the development of the data models included in the DSS needs data to be designed and implemented, we will use a data simulator while the sensors and apps are not ready.

The data is collected and a first analysis containing the preprocessing of the data is performed. The main components of the DSS are built in a threefold framework devoted to provide the intelligence to the system.

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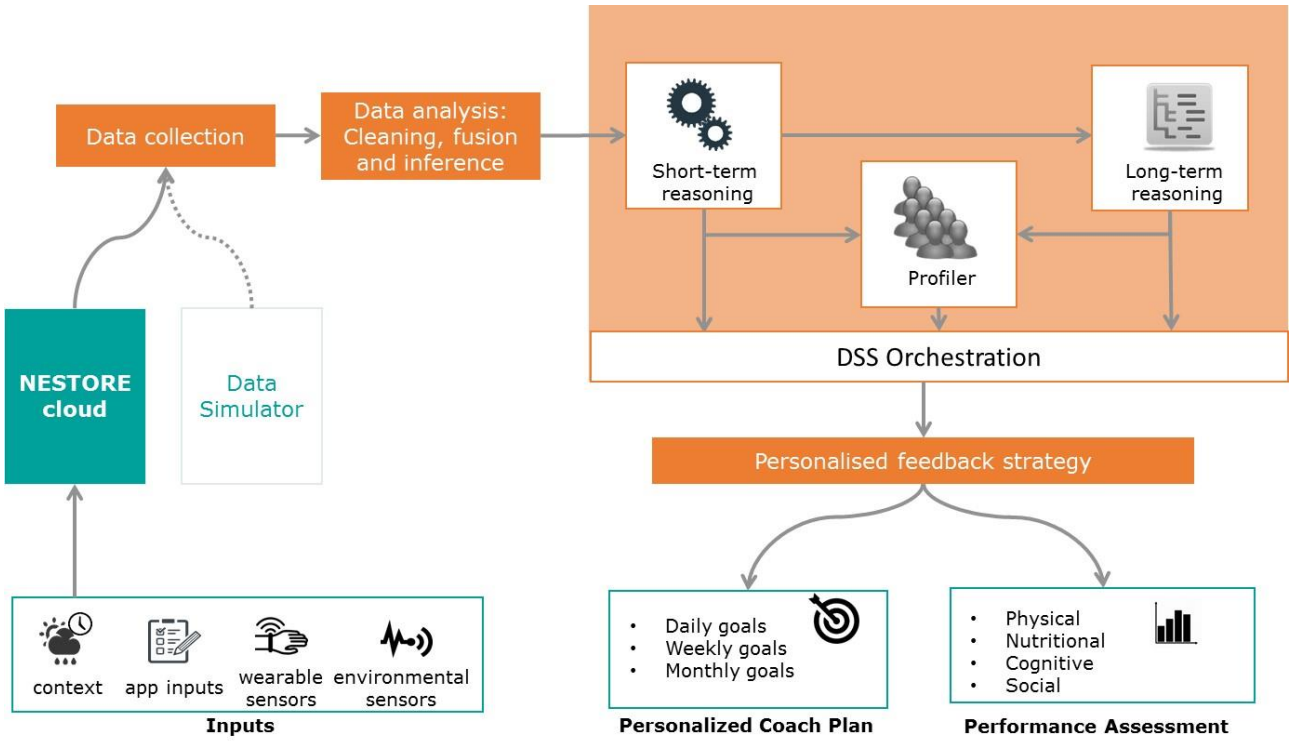

Figure 2: DSS arcitecture

On one side, a short-term analysis devoted to process the data and mine it to extract valuable indicators. This module will provide tailored feedback based on integrated information sources. It has the following objectives:

- To retrieve sensing information collected by the NESTORE platform;
- To design and implement analytic tools for measuring short-term indicators from social, environmental, nutritional and physiological measurements. Concretely:
    - physiological status and physcial activity domain: raw data from wearables or environmental devices could be analyzed and produce daily report on the physical status.
    - mental status and social relations: raw data from the wearable devices concerning the Bluetooth Low Energy (BLE) beacon will be analyzed by this subcomponent from all users. This could allow for detecting and measuring user's interaction with other participants. Multi beacon inside the house could increase the capability of the monitoring system accessing the position of the users inside the house as well as the place where interactions happen (e.g. living room, kitchen…).
    - nutrition domain: raw data from BLE beacon (eg. how many time users go into the kitchen, open the fridge…), but also from environmental sensor, photos, etc. could provide daily report on food intake in relation also to the physical activity domain.
- To provide the results of the analytic tools back to the DSS as input;
- To acquire and infer the necessary data to profile the user.

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On the other hand, long-term analysis will capture the general trend over a longer period. Intelligent algorithms aimed at studying the long timescales of users and their behavioural trend will be defined and developed. This module will be in charge of recognizing the individual behavioral habits and to predict possible declines in order to propose personalized guidelines. Concretely, it will assess if behaviour change has indeed occurred in the user, and is not just a temporary fluctuation of their habit. With this aim, trends and patterns will be extracted from daily/weekly indicators gathered in the short-term.

Finally, all the processed data will be sent to the DSS Orchestrator, which is the DSS main component. It will run in the cloud, and transform the profiles into high level indicators characterizing the user behaviour. These high-level indicators will allow the Orchestrator to generate personalized “coach plans” and suggestion consumed by the virtual coach.

As described above, DSS is a core component without any end-user interface. Yet an API will be developed for interfacing with other components of the system (i.e. Virtual Coach).

2.2.2 DSS Functional requirements

- Input data is collected from NESTORE APIs when new data is available and/or when the DSS requires it.
- DSS provide personalised “coach plans” and other type of suggestions and publish the information in APIs for being consumed by other modules of the system.
- DSS does an extensive profiling of the user to provide high personalisation of the system.
- DSS extracts short-term indicators from social, environmental, nutritional and physiological measurements.
- DSS recognizes the individual behavioral habits in long-term periods and predicts possible declines.

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Variable name	Measurement Unit	Measurement Methods	COTS* Device	TYPE of device	Wearable	Environmental	Priority for NESTORE Platform**	Data measurement frequency
Energy Expenditure								
Activity energy expenditure	%	Actigraphy, metabolimeter	YES	Metabolimeter , Camera, accelerometer, heart-rate, questionnaire	COTS: usually calculates Kcal DEV: Ad-hoc device could be implemented:	DEV: video processing algorithm for data extraction	2	
Basal Metabolic Rate	Kcal/day	Calorimetry, Actigraphy, computed, metabolimeter	YES	Metabolimeter, accelerometer, heart-rate, questionnaire	COTS		2	
Energy intake	Kcal/day	Questionnaire, camera	YES	Questionnaire and Database for foods, camera		DEV: camera acquisition of food	1	Everyday
Total Energy Expenditure	Kcal/Day	Actigraphy, metabolimeter	YES	Metabolimeter , Camera, accelerometer, heart-rate, questionnaire	COTS: usually calculates Kcal DEV: Ad-hoc device could be implemented:	DEV: video processing algorithm for data extraction	1	Continuous monitoring 24h
Nutrition habits								
Daily intake of supplements	g/day	Count	YES	Smart connected dispenser			2	
Food intake	-	Questionnaire		Analog and digital questionnaire			1	Every day
Number of meals	#	Questionnaire, camera	YES	Analog and digital questionnaire, camera		DEV: camera acquisition of food	1	Every day
Nutrition intake	ml, g, Kcal (see D2.1 Annex 2)	Questionnaire, camera, spectroscopy	YES	Analog and digital questionnaire, camera and portable food spectrometer		DEV: camera acquisition of food	1	Every day
Pathologies	List	Questionnaire	YES	Analog and digital questionnaire			2	
Refused foods	List	Questionnaire	YES	Analog and digital questionnaire			2	

Table 3: Nutrition variables

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Variable name	Measurement Unit	Measurement Methods	COTS* Device	TYPE of device	Wearable	Environmental	Priority for NESTORE Platform**	Data measurement frequency
Cognitive status								
Attention switching	score	Questionnaire	YES	Analog or digital Questionnaire			1	Once every 4 weeks
Everyday performance	score	Questionnaire	YES	Analog or digital Questionnaire			2	
Processing speed	Score	Test	YES	Analog or digital test			2	
Verbal fluency	Score	Psychometric test	YES	Analog or digital test			2	
Verbal memory	Score	Test	YES	Analog or digital test			2	
Working memory	Score	Psychometric test	YES	Analog or digital test			2	
Mental status								
Personality	Score	test	YES	Analog or digital test			2	
Social network/social integration	Score	test	YES	Analog or digital test			2	
Subjective well being	Score	test	YES	Analog or digital test			2	
Mental Behaviour and States								
Acute stress	Score	test	YES	Analog or digital test (non-standardized)			2	
Dimensional emotions	Score	test	YES	Analog or digital test (non-standardized)			1	Once every 6 months
Discrete emotions	Score	test	YES	Analog or digital test			2	
Sentiment valance detection	Score	test	YES	Analog or digital test			2	
Social Behaviour								
Interaction duration	Min	Wifi, Bluetooh, sensors			DEV: eg. iBeacon V		1	Continuous monitoring 24h
Interaction locations	Location and #	Wifi, Bluetooh, sensors		Algorithm for wifi location, sensor and Bluetooth low energy beaconing	DEV: eg. iBeacon		1	Continuous monitoring 24h
Social interactions self-report	#	Questionnaire		Questionnaires for self-reporting				
Social interactions detection	#	Wifi, Bluetooh, sensors		Algorithm for wifi location, sensor and Bluetooth low energy beaconing	DEV: eg. iBeacon		1	Continuous monitoring 24h
Total number of interactions	#	Wifi, Bluetooh, sensors		Algorithm for wifi location, sensor and Bluetooth low energy beaconing	DEV: eg. iBeacon		1	Continuous monitoring 24h

Table 4: Cognitive and Mental status & Social Behaviour variables

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2.3 Serious Game

Serious game is a game designed for a primary purpose other than pure entertainment (Abt Abt, 1987). Serious game shares aspects with videogames generally, but explicitly emphasizes the added pedagogical value of fun and competition with some other "more serious" aspects such as physical activity (e.g. Zombie Run!) (Kumar, 2013) or Nutrition (Runtastic Nutrition Quiz) (Smeddinck, 2016). Through game mechanics, games foster social connections, encourage physical activity and stimulate cognitive processes. At the same time, theu produce data about progress or loss of cognitive function.
Serious games can stimulate users in various ways; for this reason, their requirements needs explorations (task 5.1). For example, different ways of social connectivity could be explored, for instance playing a game in the same physical space (multiplayer in the same room) or together over the social network.
As described above, physical activity and cognitive are the most used domain in serious game: data from physical activity should be used to adapt different type of exercise to the users' abilities. Moreover, serious game could be used to address cognitive processes for example through reasoning and logic puzzles, visual acuity mechanism and other cognitive which will be defined by T5.1.
Starting from these points, specific designs of the games collection will be based on workshops with the users to determine the types of interaction (tangible interfaces, smartphone, AR/VR, …), platform and themes of the games.

2.4 Virtual Coach

All the variables, processing and suggestion overseen in the above paragraphs are summarized and reported to user by means of NESTORE app which is the main interface for accessing the NESTORE virtual coach.
Interactive Virtual Coach is an interface for users which reports acquired data and, by means of integration with DSS components, shows recommendations. From the point of view of the users, the virutal coach is a companion, which will be both on smarthphone or tangible interface, which allows for interacting with the system, receiving suggestion and requesting help and advice based on the user behaviour. NESTORE app will provide an interface for user profile, activity recommendations, educational content, monitoring of ongoing activities and exercises in the three different domains. Suggestions and recommendations need to be given to the users in different ways, depending on situations. Mobile device displays are not always the right solution: a more physical interaction can increase the engagement of users and result more user friendly then a touchscreen. NESTORE platform needs at least three different virtual coach interaction ways:

1. Display
2. Tangible/Physical
3. Voice

For the point of view of development, the first one is the simple one: most of mobile or portable electronic devices include display (touch or not). This solution is the least natural despite every day we are used to interact with this kind of devices.
Tangible or physical interfaces and conversational agent are devices which allow user to interact with NESTORE platform in a natural way. Users can interact with touch, smell, voice to ask and receive answers or suggestion based on data gathered by means of monitoring system. These kinds of interactions allow users who are not used to technology to take advantage of NESTORE platform.



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3 Non-functional requirements – Security and Privacy requirements

3.1 General Data Protection Regulation - GDPR

3.1.1 Introduction to GDPR

With the new EU General Data Protection Regulation, the rules regarding data protection of EU citizens' data have been harmonized better than directive 95/46/EC did. The main concept of the regulation is that the protection of personal data is a fundamental right.
Based on the GDPR framework, NESTORE solution will embrace by default the security first design (i.e. Encrypt the data in transit/at rest, implement pseudonymization, protect data integrity, Log access to personal data), as well respecting following features: Forgot Me, Export User Data/See all my data, (Re)Request Consent.
Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified. (Article 8(3) of the Charter of Fundamental Rights.) Both of these rights are essential in the sector of healthcare and they are further specified in the GDPR (Articles 15 and 16 of the GDPR).
On the present document we outline what are the most important features of the GDPR that must be followed by NESTORE consortium. Due to the novelty of the GDPR in some cases tools or specific guidelines (for partners) are not yet available and will be updated as soon as are developed.

3.1.2 General Data Protection Regulation – GDPR

NESTORE is producing software in the field of digital health and by their very nature, health applications collect and manage extremely sensitive data and therefore need to comply with security and privacy requirements defined by data protection laws such as the General Data Protection Regulation (GDPR) in EU (for US : Health Insurance Portability and Accountability Act (HIPAA)).

3.1.3 Digital health apps and data protection

The EU GDPR framework harmonizes the rules regarding data protection of EU citizens' data and is mandatory for all actors on the market.

GDPR defines high level requirements that each EU state member must implements; national laws define details that must be respected. Other laws are a must to be respected i.e. ePrivacy Regulation – or the new Cookie law envisioned for 2019.

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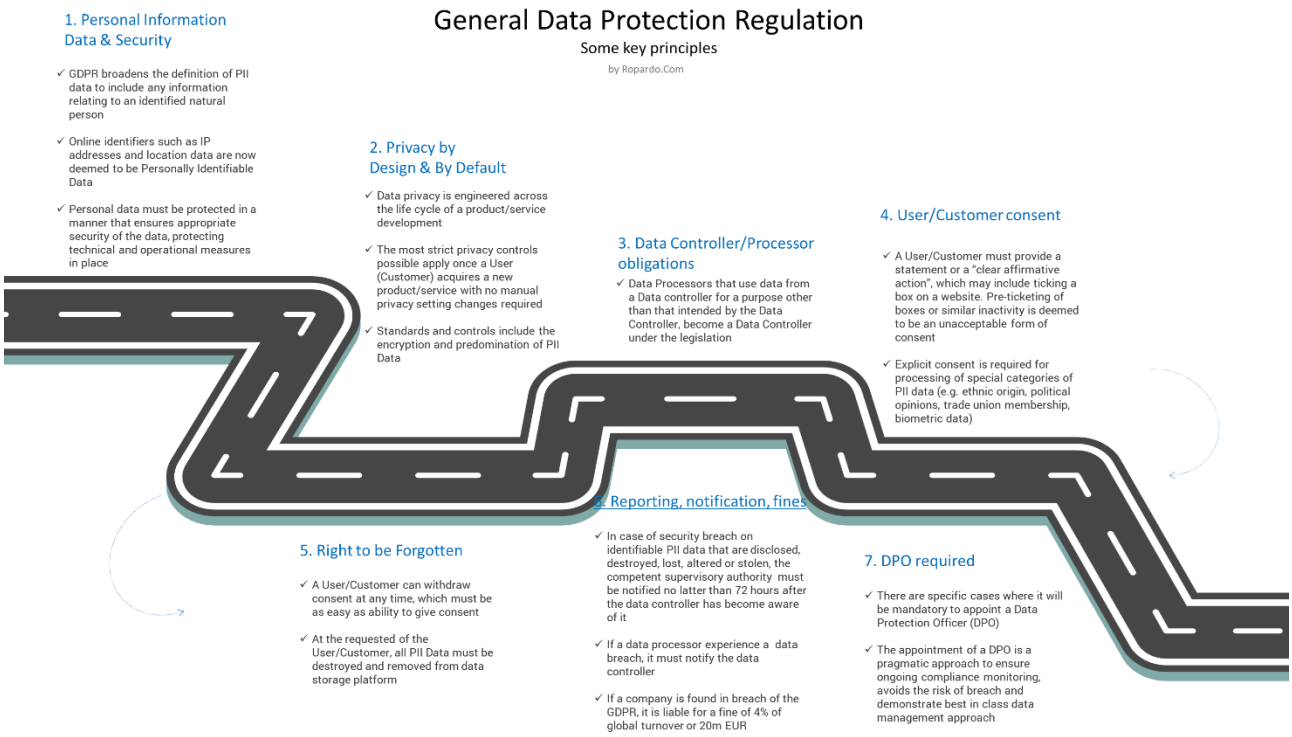

Figure 3: GDPR Key Principles

Based on the actual EU laws that provides formal definitions, some grey-areas can appear like in case with wellbeing data (i.e. physical activity) and create possibility for subjective interpretations.

Main question is how to demonstrate security compliance to whoever asks you: customers, regulators or Data Protection Authority (DPA) from your country. That means complex legal requirements / obligations. (Developers are liable for health apps compliance (tech and legal))

This definition is further explained by the Art. 29 Working party, which distinguishes Health Data in some other subcategories:

- Medical Data: providing information about the physical or mental health status of someone (the data subject), generated in a professional medical context;

Raw Data: collected by apps or devices, that can be used to induce, individually or aggregated with others, someone's health status or risk;

- Data that allow to deduce Health Status: obtained regardless of the accuracy, legitimacy or adequacy of this deduction.

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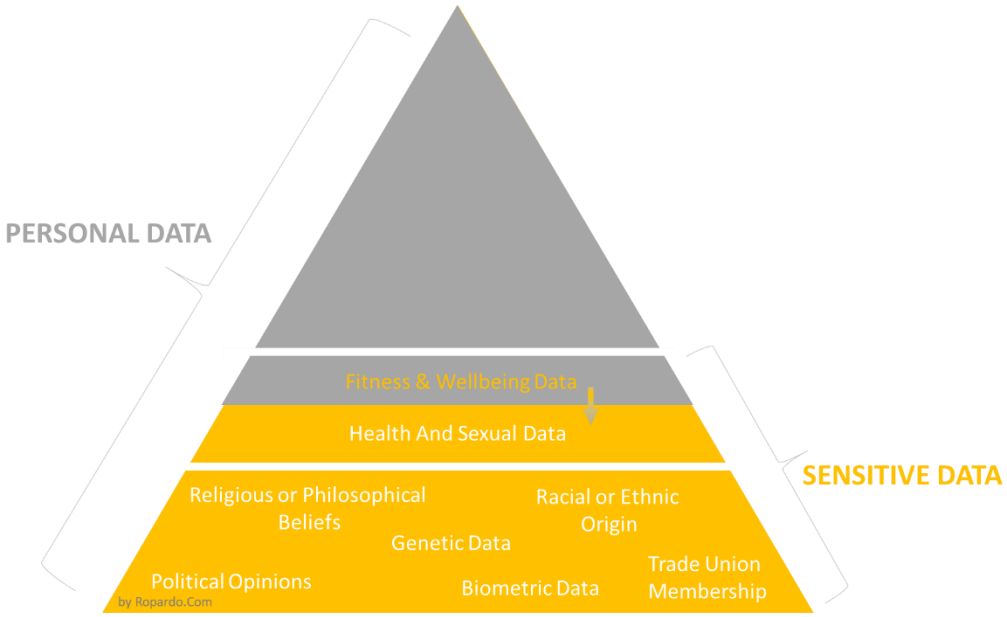

Figure 4: Data categories

Example:

Not Sensitive:

- A fitness app counts a person's steps, in the case that data cannot be combined with other data, and if the specific medical context in which the app is used is not available, then this data is not sensitive.

Sensitive:

- If the data can be easily combined with other data-sets, like the heart rate, it can reveal sensitive information about a person's ability to perform stressful activity, and thus stretches into the sensitive health-category.

3.1.4 GDPR Levels and Technical Measures

GDPR topic must be addressed on different levels and main categories can be identified as follow:

1. Organizational measures
2. Technical measures

Implementing technical requirements demands significant amount of work, knowledge, and time.

Physical requirements must be also addressed for both situations local equipment's that collect sensitive data as well for cloud datacenters/infrastructure.

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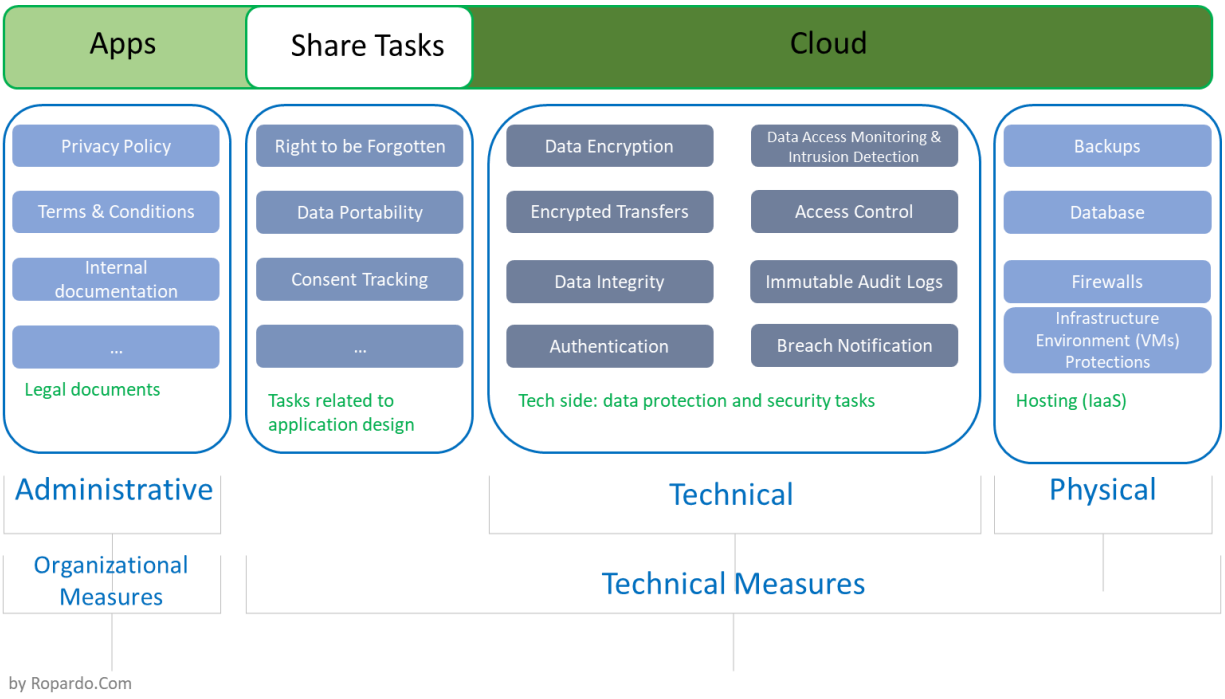

Figure 5: GDPR Levels description

3.1.5 Subjects responsibilities

It is fundamental to understand the service delivery chain and to identify who's the subject responsible for the processing of data under GDPR.

- Data Subjects
- Data Controllers
- Data Processors

Simply say:

- Data controller is someone who determines the means of processing personal data (the actual beneficiary of data, someone controlling, reviewing, comparing and aggregating the data).
- Data processors store, digitize, and catalog all the information on behalf of data controllers

In some cases, especially when a company stores the data on its own infrastructure and has total control over the data, roles of data controller and data processor overlap and are fulfilled by one entity.

NESTORE Cloud can be a Data Processor since it provides a set of services to App's. If Apps are delivering a service to a hospital, and then the hospital delivers your services to its users, then you are would be nominated as Data Processor.

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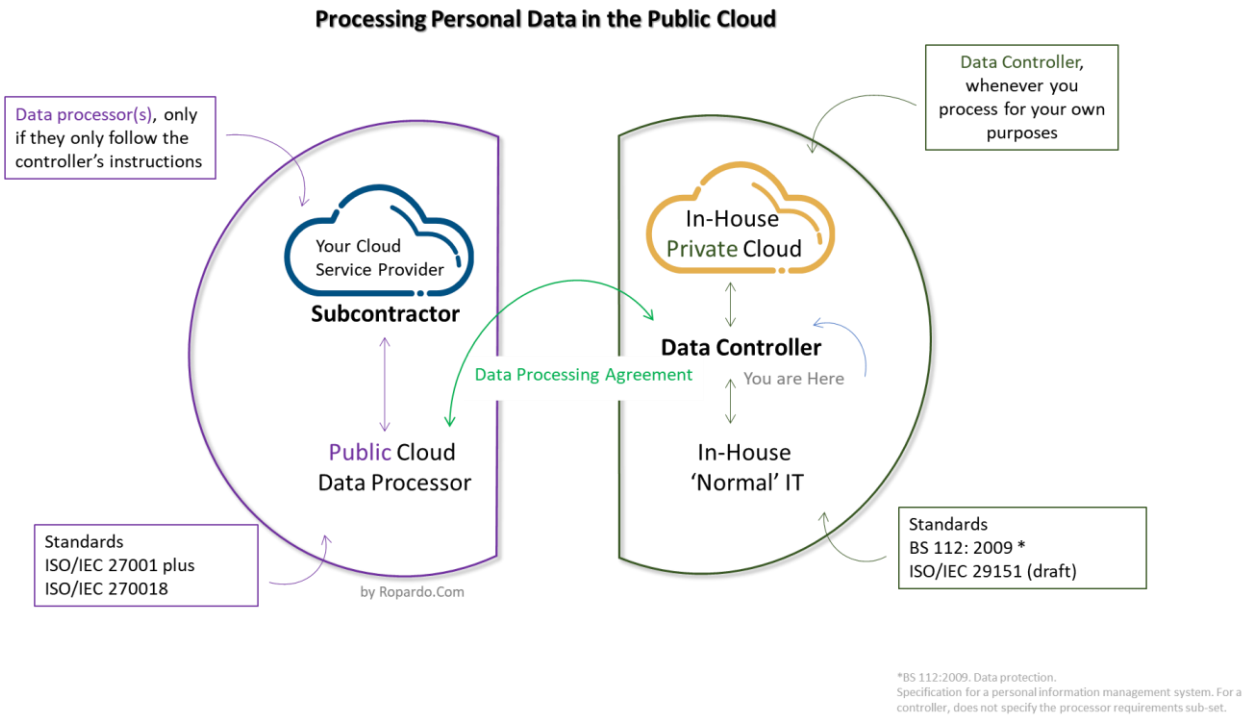

Figure 6: Processing personal data - in the public cloud

In case that are used any public cloud, service providers must be noted that responsibility of each part is stipulated in the contract. i.e. https://aws.amazon.com/compliance/shared-responsibility-model/

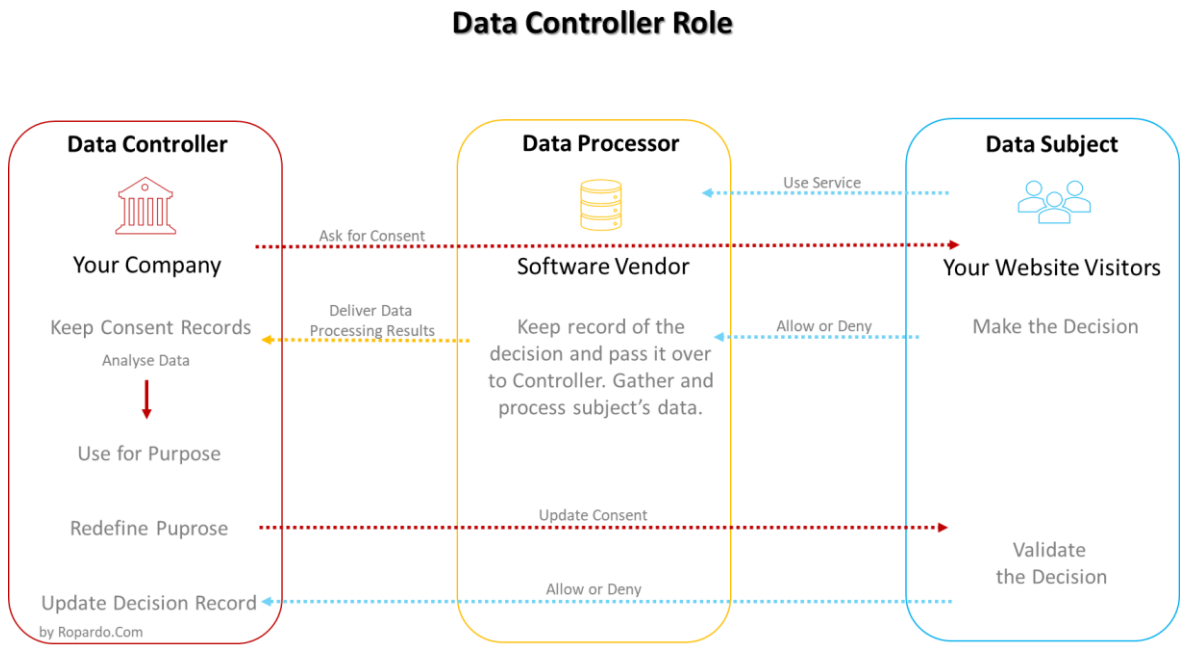

Figure 7 Sample of User Consents process

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All processors/controllers are required to:

- Only process personal data on instructions from the controller and inform the controller if it believes said instruction infringes on the GDPR (28.3). In other words, a data processor may not opportunistically use or mine personal data it is entrusted with for purposes not outlined by the data controller.
- Obtain written permission from the controller before engaging a subcontractor (28.2), and assume full liability for failures of subcontractors to meet the GDPR (28.4)
- Upon request, delete or return all personal data to the controller at the end of service contract (28.3.g)
- Enable and contribute to compliance audits conducted by the controller or a representative of the controller (28.3.h)
- Take reasonable steps to secure data, such as encryption and pseudonymization, stability and uptime, backup and disaster recovery, and regular security testing (32.1)
- Notify data controllers without undue delay upon learning of data breaches (33.2)
- Restrict personal data transfer to a third country only if legal safeguards are obtained (46)

3.1.6 User Rights

The protection of personal data is a fundamental right. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.(Article 8(3) of the Charter of Fundamental Rights.) Both of these rights are essential in the sector of healthcare and they are further specified in the GDPR (Articles 15 and 16 of the GDPR).

Data subjects also have a right to erasure ('right to be forgotten') and the right to data portability. (Articles 17 and 20 of the GDPR) Moreover, there is a right to impose a 'restriction of processing' e.g. where the accuracy of the personal data is contested by the data subject.(Article 18(1)(a) of the GDPR. Presumably, national laws or programs may exist to maintain the integrity and trust into the data in electronic health records.)

- Right to be informed
- Right to be forgotten
- Right object
    - A special rule applies in case of data processing for scientific, historical research purposes or statistical purposes. In this case the patient has the right to object unless the processing is necessary for the performance of a task carried out for reasons for public interest. (*Article 21(6) of the GDPR*) Also here, Member State have relative wide margin of discretion. Therefore, it is essential that the patient in country A is informed about the differences of regimes in Member States for this kind of further processing.
    - In addition, Member States have the possibility to restrict the right to object by legislative measures, but these restrictions must always respect "the essence of the fundamental rights and freedoms" and be necessary and proportionate measure in a democratic society to safeguard".

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3.1.7 Public health and scientific research

Member States may allow processing of personal health data for public health purposes (such as ensuring the quality of health care and protecting against health threats) and more specifically for research purposes as well as statistical and archiving purposes.

These legal grounds for processing are described as follows in Article 9(2) of the GDPR:

(i) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;

(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Both of these legal grounds require the national law to provide for suitable and specific privacy safeguards. Special safeguards apply in case of processing for scientific research purposes. (The GDPR lays down reinforced privacy safeguards for such further processing, e.g. various technical and organizations measures such as pseudonymization (Article 89))

This effectively means that the safeguards may vary from Member State to another while the basic safeguards of the GDPR provide for a minimum level of data protection. (*Article 89(2) expressly recognises the right of Member States to derogate from the right of rectification (Article 15), right of restriction of processing (Article 18) and the right to object (Article 21) in case of processing for scientific and historical research purposes or statistical purposes.*)

As a main rule, GDPR stipulates that processing for scientific research purpose shall be considered compatible with the initial purpose, such as processing for personal healthcare.(*Article 5(1)(b) GDPR*)

However, where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose (and with any relevant further information). (*Article 13(3) and 14(4) GDPR*)

However, where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose (and with any relevant further information). (*Article 13(3) and 14(4) GDPR.*)

Again, in line with the principle of mutual recognition (see Chapter 1.3. and 5) and noninterference with national law, each processing of personal data should happen in accordance with the law of the relevant Member State.

Transparent information should be available on the regimes of secondary processing in each Member State. The patient should be informed about these regimes in each country. In such a way the patient has a possibility to refuse the processing of his/her personal data in a given country.

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3.1.8 Directives & laws

The reference website for updates about Data Protection in the EU is: http://ec.europa.eu/justice/data-protection/

The reference website for updates about Cyber Security strategy in the EU is: https://ec.europa.eu/digital-agenda/en/cybersecurity

3.1.9 EU Data Protection and cyber security

Regulation (EU) 2016/679 of the European Parliament and of the Council of the 27th of April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)(Text with EEA relevance)

Directive 95/46/EC of the European Parliament and of the Council of the 24th of October 1995 (the Data Protection Directive) Harmonises national laws which require high-quality data management practices on the part of the "data controllers" and the guarantees of a series of rights for individuals. It provides generic description about categories of data and general data protection principles. It doesn't mention security safeguards and it has been defined many years ago so it does not mention topics such as as the Cloud. It will be improved by the forthcoming GDPR.

Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data of the 18th of December 2000. It regulates the processing of individuals' personal data when the processing is taking place by Community institutions and bodies.

Directive 2009/136/EC of the European Parliament and of the Council of the 25th of November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services.

Council Framework Decision 2008/977/JHA of the 27th of November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters.

Agreement on the first EU-wide legislation on cybersecurity of the European Parliament, the Council and the Commission. (12/2015).

3.1.10 Other relevant documents and opinions

Art. 29 Working Party document

- "ANNEX - health data in apps and devices"
- letter on the scope of the definition of health data in connection with lifestyle and wellbeing apps (criteria to determine when personal data qualifies as "health data").
- Opinion 06/2014 on the notion of legitimate interests of the data controller under Article 7 of Directive 95/46/EC
- Opinion 3/2013 on purpose limitation, Adopted on the 2nd April 2013, wp 203. (2013)
- Working Document 01/2012 on epSOS, Adopted on the 25th January 2012, wp 189. (2012)

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- Opinion 15/2011 on the definition of consent, Adopted on the 13th July 2011, wp 187. (2011)
- Future of Privacy: joint contribution to the Consultation of the European Commission on the legal framework for the fundamental right to protection of personal data, wp 168. (2009)
- Document on the processing of personal data relating to health in Electronic Health Records (EHR), Adopted on the 15th February 2007, wp 131. (2007)

EDPS Opinion 01/2015 on Mobile Health - Reconciling technological innovation with data protection. (5/2015)

EU Commission Green Paper on mHealth (4/2014)

Overview of the national laws on electronic health records in the EU Member States (2014)

Legal framework of Interoperable eHealth in Europe (2009) analyzes legal and regulatory frameworks for electronic health delivery and services in each Member State.

EU Commission Justice Studies on Data Protection including single country reports.

EU Commission Comparative Study of different approaches to new privacy challenges in particular in the light of technological developments (2010)

ENISA: Security and Resilience in eHealth Infrastructures and Services investigates the approaches and measures to protect critical healthcare systems.

Handbook on European data protection law by the European Union Agency for Fundamental Rights (FRA) and the Council of Europe together with the Registry of the European Court of Human Rights.

3.2 GDPR Compliance checklist

This paragraph shows the checklist that is required for the GDPR compliance of the NESTORE platfrom. The checklist is divided into the five parts which compose the GDPR regulation: Personal Data, Data Processing, Data Storage, Data Transfer and Location and Data Security,

3.2.1 Personal Data:

GDPR regulation modifies the meaning of personal data widenessing the concept. Personal data means anu information concerning an identified or identifiable natural person, that can be used to directly or indirectly identify the person. It can be anything from a name, a photo, an email address, posts on social, medical information or a computer IP. The Regulation does not apply to personal data rendered anonymous so that the data subject is not identifiable.

Requirements to be verified and validated in NESTORE platform:

- Identify types of personal data collected;
-
- Identify sensitive data;

3.2.2 Data Processing

Processing of data must be lawful, fair and transparent. Users should be aware of the risks, rules, safeguards and their rights in realtion to the processing of personal data. Regulation requires also to specify the purposes for which personal data need to be processed. Time limits should be estabilished for erasure or periodic review. Moreover, personal data should be processed in a manner that ensures appropriate security and confidentiality.

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Requirements to be verified and validated in NESTORE platform:

- Appoint data protection officer (DPO)

- Confirm the lawful basis for the processing:
  - Consent
  - Necessary for compliance with a legal obligation to which the controller is subject
  - Necessary for the performance of a contract to which the data subject is a party
  - Necessary to protect an individual's vital interest
  - Legitimate interests of the controller (i.e. providing client services or preventing fraud)
  - Transfers of personal data among controllers within an affiliated group for internal administrative purposes
  - Strinctly necessary and proportionate for ensuring network and information security

- If consent is the basis for the processing:
  - Must be unambiguous, specific and freely given
  - Must obtain consent for each processing activity and purpose
  - Explicit consent required for sensitive data
- Confirm that personal data collected is limited to what is necessary for the purpoeses

- Determine whether a data protection impact assessment (PIA) is required:
  - Systems that analyze personal economics, location, health , peformances, reliability or behaviour
  - Video surveillane systems
  - Data in large scale filing system on childrem genetic or biometric data

- PIA should address:
  - Contemplated processing and purposes
  - Necessity and proportionality of the processing in realtion to the purposes
  - Risks to the rights and freedoms of data subjects
  - Safeguards and security measures to address the risks

- If PIA indicates that processing would result in high risk, then consult DPA prior to processing

- Data subjects must be informed about:
  - Identity and contact information for controller and DPO
  - Purposes of the processing and legal basis
  - Recipientsand categories of recipients of pernsal data
  - Period for which personal data will be stored
  - Right to request access to personal data or to restrict processing for correction and erasure
  - Right to withdraw consent at any time
  - Right to file complaint with supervisory authority

- Review privacy policies

- Estabilish system for documenting processing operations

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3.2.3 Data storage

As well as providing information on how data is saved and where, GDPR requires technical and organizational measures to prevent data breaches and subsequent damages. Privacy is required to be implemented during design and not as anaddition. Moreover, breach notification is mandatory where it is likely to "result in a risk for the rights and freedom of individuals" within 72 hours of first having become aware of the breach. Regulation expects also for controllers to hold and process only data which are absolutely necessary, as well as not to change the use of these data. Controllers need to guarantee the right to be forgotten deleting any data at the request fo data subject, and the right to access, provinding copy of personal data free of charge in electronic format.

Requirements to be verified and validated in NESTORE platform:

- Determine where and how data is stored
- Estabilish limits for erasure of data and periodic reviews
- Estabilish data retention policies to ensure data only kept for as long as necessary
- Estabilish processes for rectifying or deleting inaccurate data
- Prepare temoplate rensposes for data access request and removal.

3.2.4 Codes of Conduct

Codes of conduct are encouraged, and are subject to approval by the Commision, and complicance should be monitored by an appropriate expert or accredited body. Approved codes of conduct need to be registered and published. Data protection certification mechanism, seals and marks are encouraged.

Requirements to be verified and validated in NESTORE platform:

- Codes of conduct and certification mechanisms

3.2.5 Data transfer

GDPR regulates data rtransfer between different countries. Transfer are permitted based on a determination that the country provides adequate protection of privacy.

Requirements to be verified and validated in NESTORE platform:

- Estabilish, review and analyze data flows
- Determine robust and valid mechanisms when necessary to transfer pesonal data from EU to US or other countries

3.2.6 Data security

Beside Data transfer, GDPR regulates Data Security in term of protection, data loss , encription…

Requirements to be verified and validated in NESTORE platform:

- Define techncial and organizational measures to prevent unlawful destruction, loss, alteration, disclosure of/access to persoanl data
    - Pseudonymization and encryption

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- Ability to ensure ongoing confidentiality integrity, availability and resilience of processing system and services.
- Ability to restore availability and access to data
- Process for regularity testing, assessing and evaluating the effectiveness of the security measures in place

- Ensure that processors are employing adequate technical and organizational measures; address in contracts

- Estabilish data breach rensposne plan

3.3 Wearability and Usability

The term "wearability" is strictly related to wearable devices and describes the capability of the sensor to be comfortable dressed without modifying any of the variables which the device is recording.
It has been almost 20 years since Gemperle et al. wrote "Design for Wearability" (Gemperle, Kasabach, Stivoric, Bauer, & Martin) which scientific community try to create guidelines and reasons for on-body location depending on the use of a wearable technology.
This section reports possible optimized positions on body for wearable device based on data to be captured.

For sensing whole body motion by means of accelerometer, gyroscopes and magnetometers, devices can be placed on different parts of the body, but only some position are optimized for full body movements. Here are some considerations related to movement sensor placement (see Figure 8):

- For capturing whole body motion, Inertial Motion Unit (IMU) should be placed close to the center of gravity (e.g. on the chest).
- For capturing motion of limbs, IMU should be placed on the limbs. Combinations of sensors in lower and upper limb configurations can aid in more defined movement capture
- For capturing motion with respect to the environment, magnetometer and barometric sensor should be used.
- For flex/bend and force measuring, flex and pressure sensors should be used directly on joints and points of measurement. These particular sensors need more attention in term of wearability and comfortability because can influence the users' movement freedom.

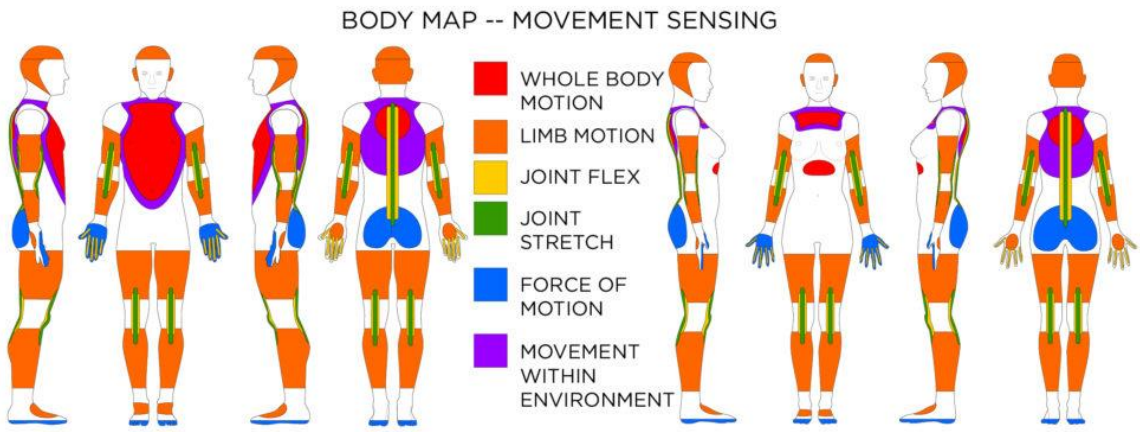

Figure 8: Body map for sensing body motion

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Figure 9A shows body map for heart rate. It consider both two most used methods: electrocardiography and photo -plethysmography. For the first method, the most used position is the chest, while for PPG is the wrist or the forearm. Blood pressure maps (Figure 9B) is usually measured on the arm, but there are some specific sensors (as described in Table 2) which can be placed on the forearm; these sensors are more comfortable, but have a lower reliability. Respiration and temperature sensor are those with more stringent positions requirements as shown in Figure 9 C and D.

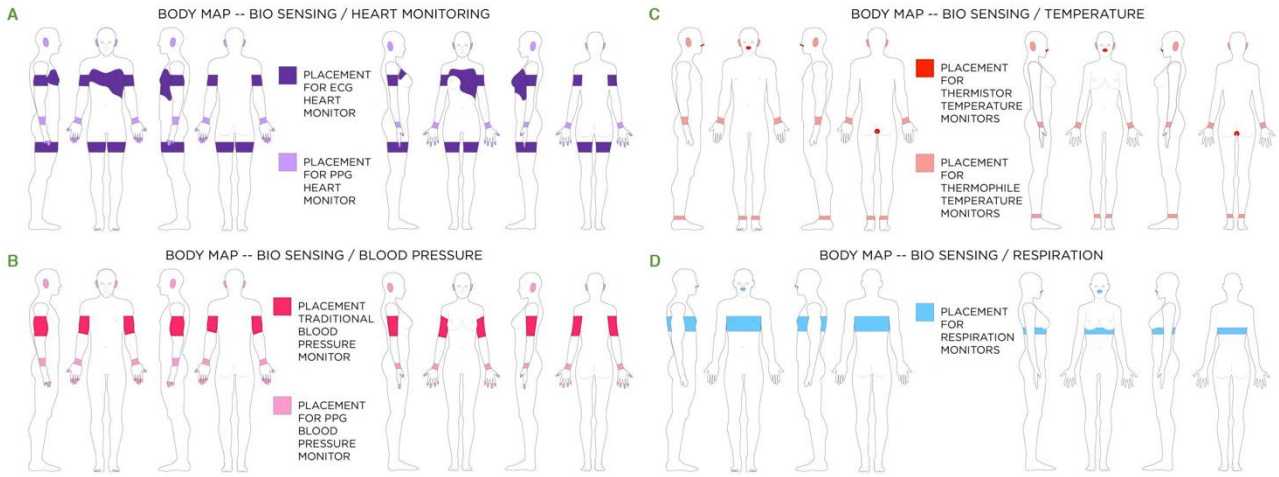

Figure 9: map for biosensing devices positions

Zeagler, 2017 reports different maps for device wearability. As well as the maps for sensing body motions here are reported maps for body motion impedance due to wearable devices (Figure 10), maps for bio sensing (heartrate, blood pressure, temperature and respiration) and a more general map that is a combination of the the most frequent reasons for wearable technology, functional, technical, and social considerations in on-body location with the affordances offered to technology by different locations on the body.

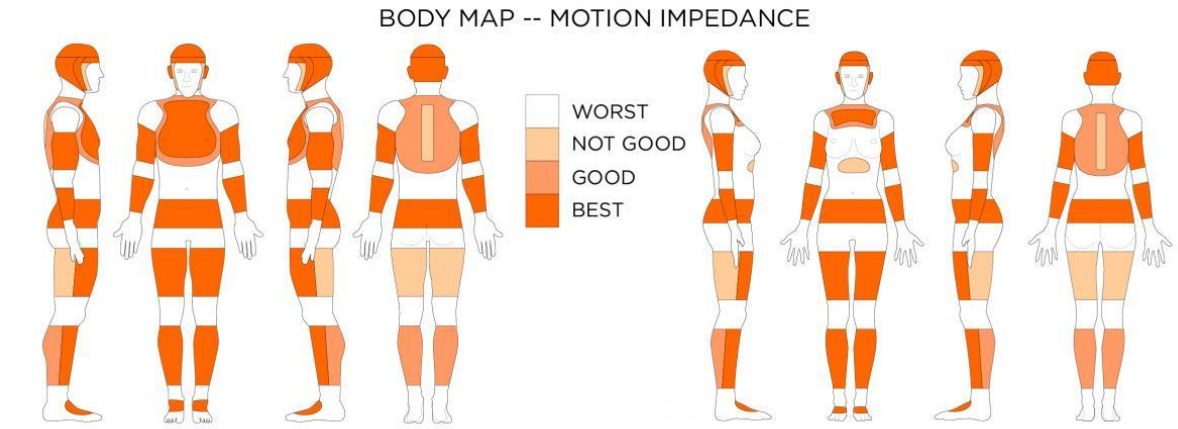

Figure 10: Map for the best places to place wearable device based on movement obstruction

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Wearability is closely related with usbaility: a wearable device which is not comfortable probabily will not be accepted neither used in the correct way.
Define usability requirements earlyer imporve the quality of the system becouse developer con include them directly in the early development phase and can be tested later in the development process.
Relavat usability requirements are reported below.

Uderstandability:
NESTORE platform has been meant for adult people in the threshold of seniority. These people have experienced in their lifes the transition between the analogue and the digital world, but they are not necessarly technology addicted. It is necessary that the NESTORE interface is composed by elements which are easy to understand, clear and functional, always keeping in the foreground what the purpose of the platform is.

Learnability
NESTORE platform is realy complex becouse built upon different subsystem and domains. The platform need to be easy to learn, with a complete user documentation and help which are context sensitive and explain how to achive common tasks (e.g. add a meal, connect devices…)

Operability:
Operability means the ability to keep the platform in a safe and reliable functioning condition; this consists in simple task which can sometimes be understiamted: error message which explain how to recover from the error; undo available for most actions; consistent interfaces; customisable system to meet specific user needs, ask confirmation for undonable actions.

Attractiveness:
Nestore interfaces are the main “connection” between users and the platform. Interface need to be clear, user friendly and at the same time appealing in order to engage the user and encourage him to continue using the platform.

More information on settings criteria for effectiveness and satisfaction cab ne found in ISO 9241-11.

Usability need to be verified during the development process by means of focus groups, interviews but also standardized methods like SUS, QUIS and other already verified questionnaires.-

3.4 Platform communication and technological requirements

As described in the above chapters, NESTORE platform is composed by multiple devices which can be connected by means of different communication technology. Experts questionnaires allow for understanding the requirements in term of communication technology and devices. Different modules of NESTORE platform (see Figure 11) requires different kind of communication technology. For this reason, TABLE 4 reports a summary of the requirements for most of the modules in order to proceed with the platform architecture’s drafting.

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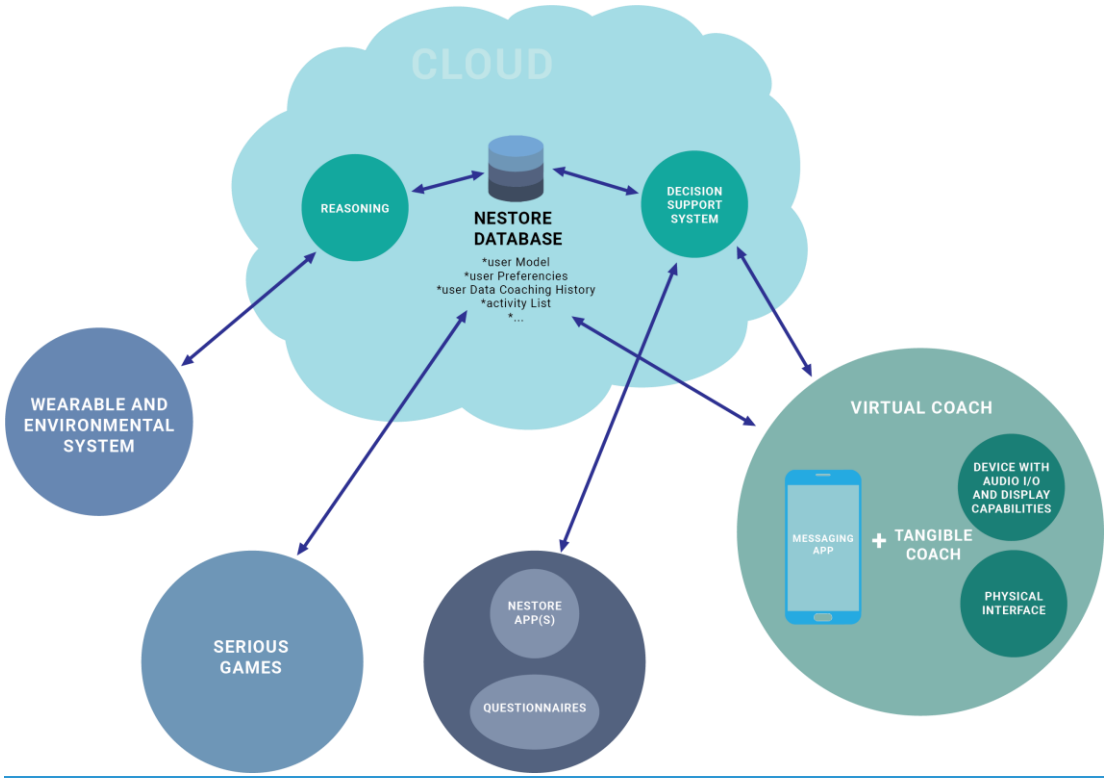

Figure 11: Overview of NESTORE platform modules

This table is a summary of the communciation technology which are required by all the modules.

Requirement	Wearable monitoring device	Environmental monitoring device	Decision Support System	Virtual Coach	Game	Tangible interface
Internet connection	NO	Yes, environmental monitoring system sends data to the cloud continuously.	Yes, DSS runs both locallly and in the cloud	YES, Virtual coach received data from DSS	YES, for data syncronization with other Nestore modules.	Yes, it receives data from DSS
Cloud storage	YES, if history is required. GDPR compliance required.	YES, if history is required. GDPR compliance required.	YES, required for long term analysis.	NO	YES, for leaderboard and game data synchronization,	NO
WiFi	NO, it require to much power and battery.	YES, if device is connected to the plug.	-	-	-	YES, if the device is connected to the plug
Zigbee/Z-Wave/Thread or other low energy communicaiont	YES, but requires router or dongle in order to connect wearable to PC or mobile devices	YES, but requires router or dongle in order to connect wearable to PC or mobile devices	-	-	-	YES, but requires router or dongle in order to connect wearable to PC or mobile devices. Tangible Interface could be the dongle for this kind of communication technology
Bluetooth Low Energy	YES, it could connect directly with PC and mobile devices. BLE allows for low data-rate. Only smal data could be sent in order to save battery.	YES, it could connect directly with PC and mobile devices.	-	-	-	YES
Offline working	YES, wearable could record data without any connection active and then download data when connected	YES, environmental sensors could be connected only sometimes and send data while connected.	DSS requires full-time internet access for real-time support (e.g. assess current progress in personal goals or exercises); all the other module requires a irregular connection.	YES, virtual coach uses offline DSS locally	YES, it works with local data and then re-sync when connected	YES, it works with local data and then re/sync when connected.

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Mobile phone (iOS and Android)	Bluetooth Low Energy is the most common type of communication with wearable devices	Environemtnal sensors are always in the home, it can be connected with Bluetooth Low Energy, WiFi or other low energy communication technology	Run both locally on mobile platform and on the cloud	-	-	Tangible Interface can be a modified mobile phone with hardware output, or embedded devices like Arduino Board, Raspberry Pi or Android Things.

Table 5: Summary of NESTORE platform requirements with modules and notes

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