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Version	Date	Comment
0.1	18/09/2012	TOC (ICOM)
0.2	27/09/2012	Input from IHP
0.3	30/09/2012	Input from ICOM and first release
0.4	12/10/2012	New version with input from ICOM, IHP, SOTON, RFSAT, BBK
1.0	18/10/2012	Final version with review from IHP

Executive Summary

In this document the general design guidelines related to the StrokeBack ICT infrastructure are documented. These guidelines are derived through the processing of the user requirements described in D2.1 and also the outcome of interviews and bilateral meetings with the end users of the project that took place during the first year of the project.

List of abbreviations

Abbreviation	Explanation
ADL	Activities of Daily Living
BI	Barthel Index (according to Mahoney and Barthel, 1965)
BT	Bluetooth
BT-LE	Bluetooth - Low Energy
ECG	Electrocardiogram
EEG	Electroencephalogram
EMG	Electromyogram
ICT	Information and Communication Technology
SiP	System in Package
SoC	System on Chip
SS-QoL	Stroke Specific Quality of Life scale
TI	Texas Instruments
WMFT	Wolf Motor Function Test

1 StrokeBack application scenarios

The first iteration of the StrokeBack use cases was documented in D2.1, which was due on M6 of the project. Following a set of general assemblies and bilateral meetings and remote discussions between the consortium participants towards the establishment of the architectural foundation of the project, these use cases were eventually modified and updated to better address actual user needs. In the subsequent paragraphs the reader is provided with the updated versions of the use cases that are relevant to the project.

1.1 Clinical Assessment of patient needs

The StrokeBack system is designed to be employed in a controlled environment under the supervision of a physiotherapist, or other appropriately qualified clinician, trained in its use. From a clinical point of view, the objective is to assess the patient's level of impairment and determine an appropriate exercise regime. During subsequent visits to the clinic, the patient's level of impairment will again be assessed, thereby providing a temporal measure of rehabilitation progress. This does not necessarily have to be undertaken at the clinic; it could be at the patient's home, but will always be in the presence of a clinician.

The system being used for clinical assessment of patient needs will consist of a number of body worn wireless sensors (the BAN) and a PC based motion capture system (e.g. Kinect). The choice of sensors used will be kinematic sensor modules (comprised of tri-axial accelerometers and tri-axial rate gyroscopes, which when combined give 6 degrees of freedom in measurement), EMG sensors to monitor muscle activity in the biceps and triceps and possibly an ECG sensor to monitor heart rhythm. The kinematic sensor modules will be positioned on the forearm just above the wrist, on the upper arm just above the elbow and on the sternum, though exact positioning will be determined through early stage investigations. The motion capture system will be used to film the patient as they perform specific tasks and exercises, and the temporal film record will be used as a qualitative measure of patient rehabilitation progress.

Appropriate methods to provide secure and repeatable attachment of the sensors to the body will be investigated early in the research programme as well as the effects of sensor orientation and misalignment.

Clinical assessment will initially commence with a face-to-face dialogue between the patient and clinician. From this, the clinician will be able to establish the patient's level of impairment and the patient will be able to inform the clinician as to what their personal objectives from rehabilitation are. This will enable the clinician to decide which of a range of upper limb functional tasks and exercises are most appropriate for the patient. Following on from this dialogue the measurement phase commences with the patient encouraged to perform a subset of exercises and functional tasks from the WMFT collection, which will have been specifically selected by the clinician to suit the patient's objectives and perceived capabilities.

The motion capture system will record the patient's movements during the exercises. Through suitable signal processing, the motion capture system will produce temporal and spatial kinematic information including: limb segment position in space, limb segment velocity and acceleration, joint angles, and total time for individual task completion. Within the project it will be investigated how this data can be exploited in an automated assessment of the patient's level of impairment and how the automatic

assessment correlates to the one done by the clinician. Accordingly, the motion capture system can be considered as a 'standard' against which data derived from other sensor sources can be compared.

During the execution of the exercises, data from the BAN will be directly transmitted to the host PC in real-time and processed in two different ways: first, transformation algorithms will convert the raw sensor data to 3-dimensional spatial information which will be directly compared with the data generated from the motion capture system. This will serve as a simple check on the accuracy and robustness of the transformation algorithms. The second data processing strategy will involve searching for patterns within the sensor data that exhibit high correlation with specific movements of the upper limb or specific functional tasks being performed. At a subsequent phase, these data patterns will be used by the home-based system as templates to determine whether such movements are being performed by the patient during normal Activities of Daily Living (see use case described in 1.2.3 below). Other features of the data recorded (such features to be determined) will also be used as metrics to assess rehabilitation progress. For example, this might include calculating energy expenditure from EMG data or estimating metabolic rate from ECG data.

Initially the patient will be instructed to perform a number of simple tasks that effectively move the BAN sensors through a number of predefined orientations whilst being filmed by the motion capture system. At the same time the sensors will be transmitting their data to the host PC. By comparing the sensor data with that from the motion capture system it will be possible to re-calibrate the sensors, accounting for any positional inaccuracies in sensor placement.

Then, the clinician will assess the patient whilst they perform a set of standard exercises, based on the WMFT test and use their professional judgement to rate the patient in accordance with the WMFT scoring system. This score will be entered into the PHR-S database, using a web browser based user interface. The clinician will also assess the patient's impairment and quality of life using the Barthel Index (BI) [1] and the Stroke Specific Quality of Life Scale (SS-QoL) [2] questionnaires.

All of the raw data collected from the body-worn wireless sensors as well as processed data will also be stored in the PHR-S database. Also, this PHR-S will provide web based forms to fill in the findings related to the execution of the exercises as well as to answer to the above-mentioned questionnaires.

Subsequent scheduled or ad hoc visits to the clinic will involve re-rating the patient's performance of their specific and prescribed subset of tasks from the WMFT, allowing a longitudinal measure of rehabilitation progress to be determined with clinical credibility.

1.1.1 General design guidelines

Fundamental principles of the system to be used for the clinical assessment of the patient's needs are the following:

- Will offer a diagnostic tool for identification of key impairments
- Identified by analysis of data generated during the performance of standardised tasks
- Will consist of a BAN + external sensors e.g. cameras and/or motion capture system
- Will consist of a Rehabilitation Management application for storing clinical assessment results (either manually by the clinician or automatically by the processing application)
- Offer a method of activity prescription (through the Rehabilitation Management application)

- Aim to collect large amounts of rich highly informative data
- Real time data analysis and feedback not critical
- Power consumption not critical

1.1.2 ICT infrastructure involved

The building blocks of the infrastructure involved in the realization of this use case are depicted in the following figure.

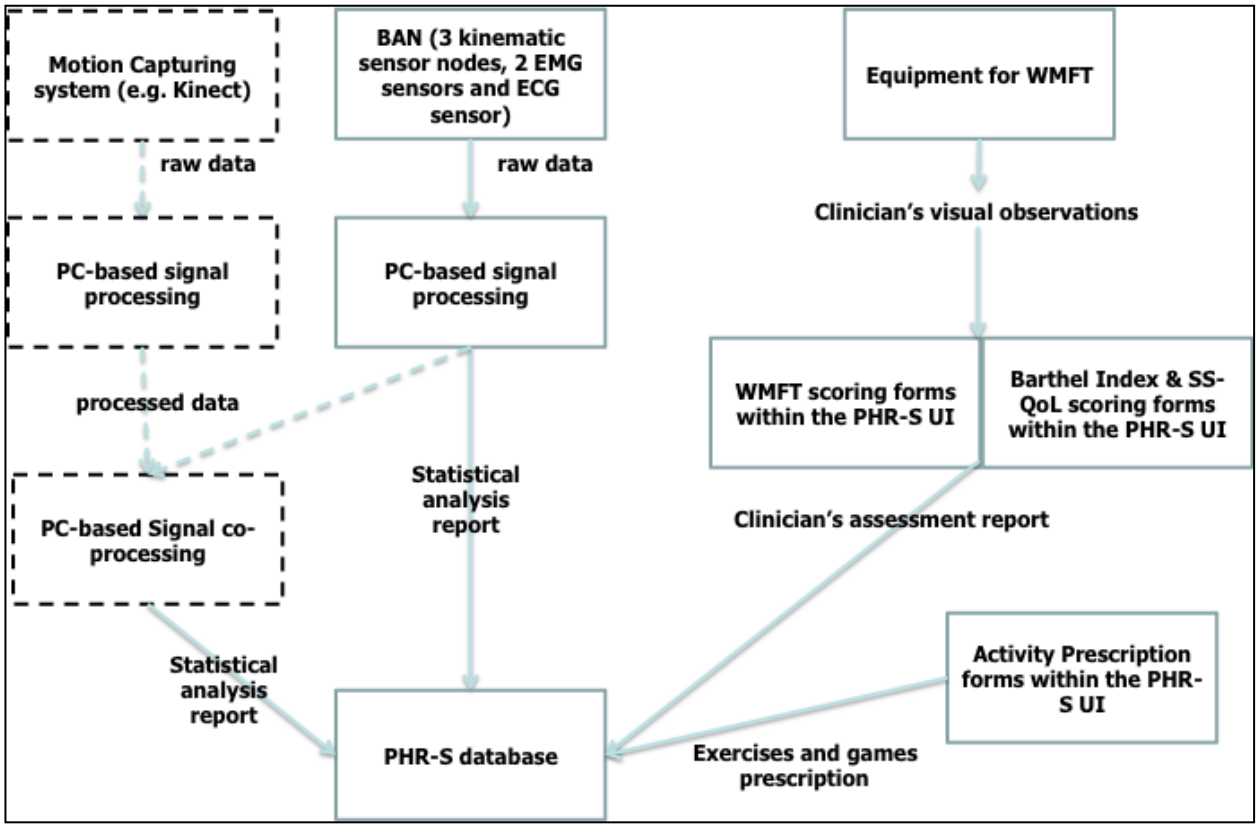

Figure 1: Infrastructure necessary for the clinical assessment use case[1]

The main components are the following:

- Single Kinect or webcam to record patient during exercises.
- BAN – comprised of three kinematic sensor nodes (each node = 3 axis accelerometer and 3 axis gyroscope), 2 EMG sensors and ECG sensor (?).
- Host PC with Bluetooth and BAN docking station, where signal processing (of data coming from the BAN and the Kinect will take place
- WMFT equipment
- (web) Interface to be used by the clinician to insert findings of his assessment, and prescribe exercises and games for the home exercise use case (see below, 1.1.3)

[1] Arrows or boxes in dashed line indicate optionality at the time of preparation of this document

- PHR-S database for persistent storage of signal processing outcomes, clinician's assessment reports, patient's exercise regime

1.1.3 Data flow related to Clinical Assesment scenario

The following data flow that corresponds to the clinical assessment is depicted in Figure 2:

1. Clinician sets up the WMFT schedule of the patient and fills in BI and SS-QoL questionnaires.
2. Real-time streaming of BAN data from all sensors.

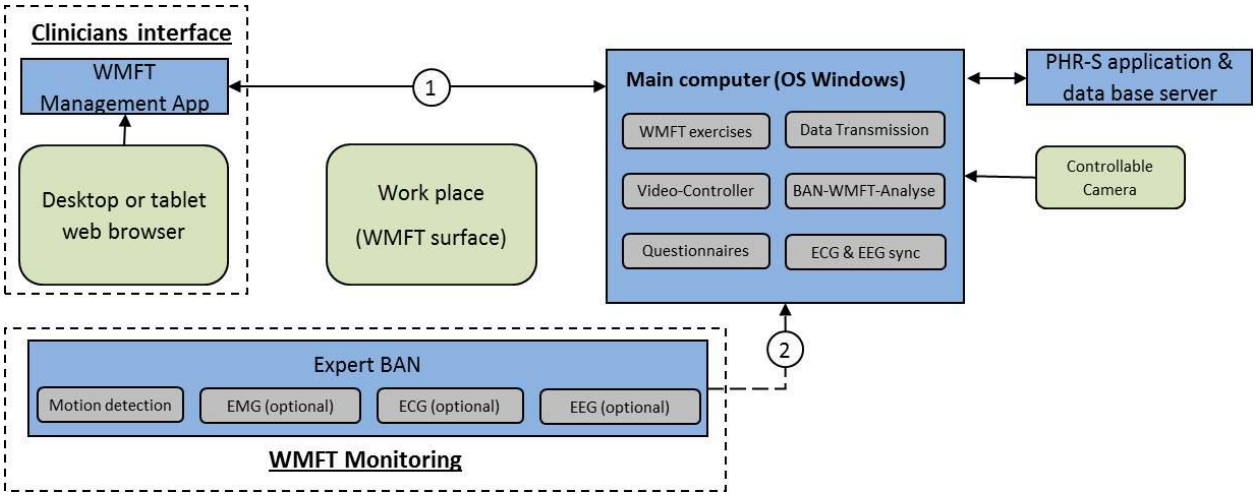

Figure 2: Data flow in clinical assessment scenario

1.2 Home exercise environment

In this use case, the home-based BAN will be used in conjunction with a PC motion capture system (Kinect) within a controlled 'measurement zone' (e.g. at a work table with a customised interaction platform). A second motion capture system will be used to monitor the execution of the exercises from the far field.

Before playing the games, the patient will most probably be instructed to perform a sequence of simple movements that will be used to calibrate the BAN sensors. These movements will consist of displacements of the upper and lower arm (up/down, left/right, forward/backward) and rotations of the upper and lower arm (clockwise/anticlockwise along all possible axes). Both Kinect systems will monitor the patient's arm movements during this calibration step and the BAN will transmit data in real-time to the host PC. The host PC will match the BAN data to the Kinect data to allow the system to determine the orientation of the BAN sensors and to calibrate their responses. The PC will also match the BAN data to the individual arm movements to learn data patterns that represent these simple arm movements. The host PC will transmit the calibration data and characteristic patterns back to the BAN. These patterns will be used in the context of the ADL use case (see below, 1.2.3) to determine the patient's activity.

After BAN calibration, the patient will be asked to perform repetitions of exercises identified as being appropriate to them during initial assessment at the clinic and eventually prescribed by the clinician using the web interface of the PHR-S. More specifically, the patient will be presented with a selection of games specific to their rehabilitation requirements. The patient will then select the game(s) they wish to

play by interacting with the smart table. The games will be displayed on a TV or PC monitor and controlled by the patient's arm and hand movements captured by the near field Kinect. Kinect data will be processed on the local host PC and does not need to be uploaded to the PHR. The BAN will record data continuously during game playing.

The far field Kinect system will record the upper body movement of the patient during the game play. If the patient makes compensatory movements with the upper body, the patient can be alerted that they are not performing the game (doing their exercise) properly. This may involve some visual representation to the patient in the form of an avatar showing the patient how they moved their arm or hand compared to how they should have moved their arm or hand.

Other relevant kinematic information will be derived from the spatial coordinate data including body segment acceleration, body segment velocity, body segment angle, body segment tremor, etc., and these will all be stored on the PC for post exercise analysis to yield quantitative measures of performance. Such performance indicators will be presented to the patient in a suitable format at the end of the exercise session (e.g. graphs, road maps, etc.). In this manner, the patient will feel a greater sense of involvement in their own rehabilitation.

Raw sensor data, processed sensor kinematic data, motion capture kinematic data and processed sensor classifying data will all be stored in the PHR-S database through an internet connection to the patient's home PC. The statistical analysis of this info will be eventually become available to the clinicians, via the PHR-S web interface in order to assess the rehabilitation progress.

1.2.1 General design quidelines

- BAN easy to put on and remains in place
- Comfortable to wear, lightweight and not restricting normal body movement
- Extended energy autonomy of the BAN
- Docking station for downloading data from the BAN and for recharging batteries
- Two motion capturing systems, one in the near field and one in the far field
- Internet connectivity to exchange info between PHR-S database and application running at the local PC

1.2.2 ICT infrastructure involved

The building blocks of the infrastructure involved in the realization of this use case are depicted in the following figure:

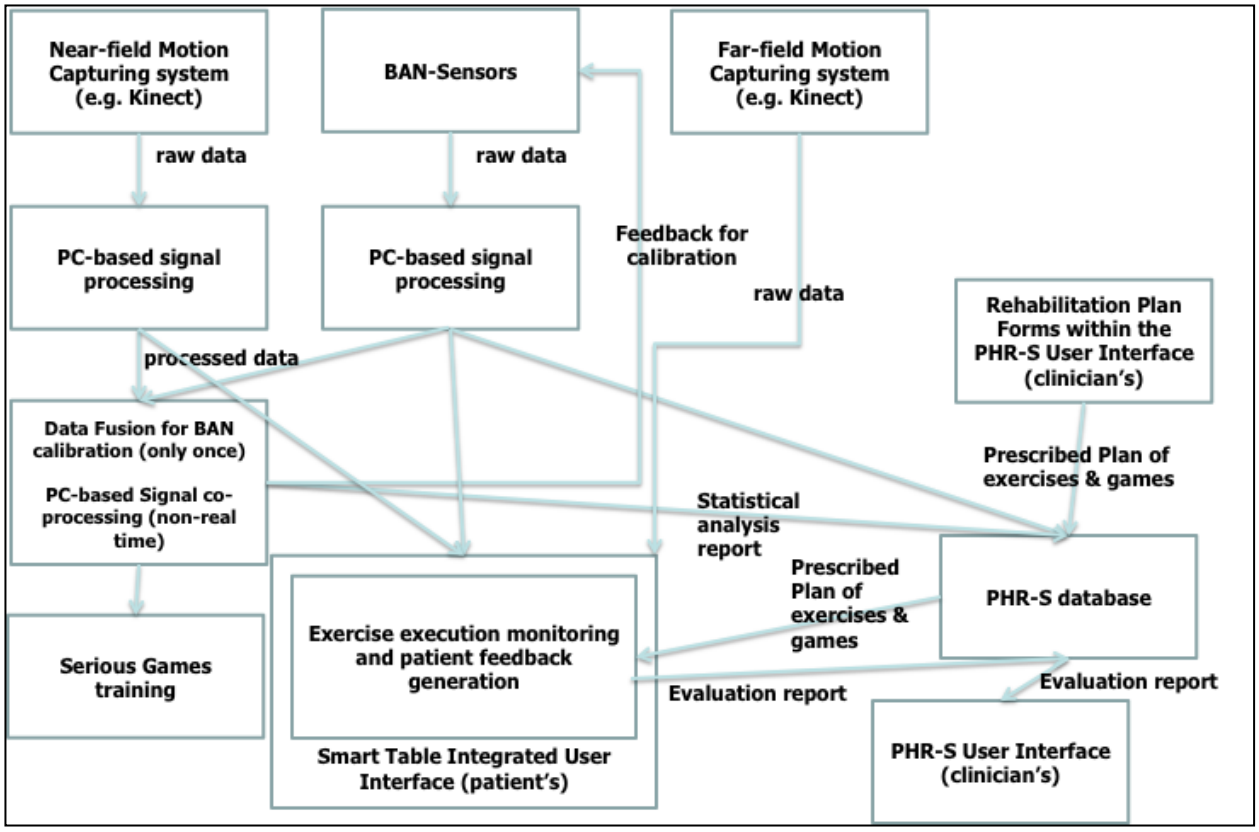

Figure 3: Infrastructure necessary for home exercise use case

The main components are the following:

- Two Kinect systems:
  - Near field – capturing patient hand and arm movement and position of objects to provide input controls for the games;
  - Far field – capturing patient's posture to determine correctness of exercises and whether the patient carries out compensatory movements.
- Equipment for video conference (webcam + microphone)
- BAN – three kinematic sensor nodes (each node = 3 axis accelerometer and 3 axis gyroscope) and 2 EMG sensors.
- Host PC where all local processing and presentation applications run
- Monitor to display games.
- Touch screen or smart table to display PHR patient interface and some games.

1.2.3 Data flow related to Home Excercise use case

The data flow that corresponds to the Home Exercise scenario is as follows, see also Figure 4:

1. Raw data from Kinect to be processed by the Kinect-Server for the Interaction Board or by the OpenNI Framework and Microsoft Kinect SDK for calculating "skeleton stream" data for the Exercise and Compensation Analyse.

2. Coordinates of objects, fingers etc. with rate of 50 frames per second to calculate movements and events for the game logic of the Interaction Board.
3. Three-dimensional coordinates and orientation data of body joints with a rate of 50 frames per second for calculating a vector-based, 3-dimensional representation model of the patients upper body.
4. Video data to screen (VGA or HDMI). It is controlled by the main application displaying PHR-content, Game-content or management content on the work place and/or the front monitor.
5. Raw or pre-classified sensor data from BAN nodes for evaluation of ADL.
6. Clinician checks and sets up the rehabilitation schedule of the patient including exercises and games.

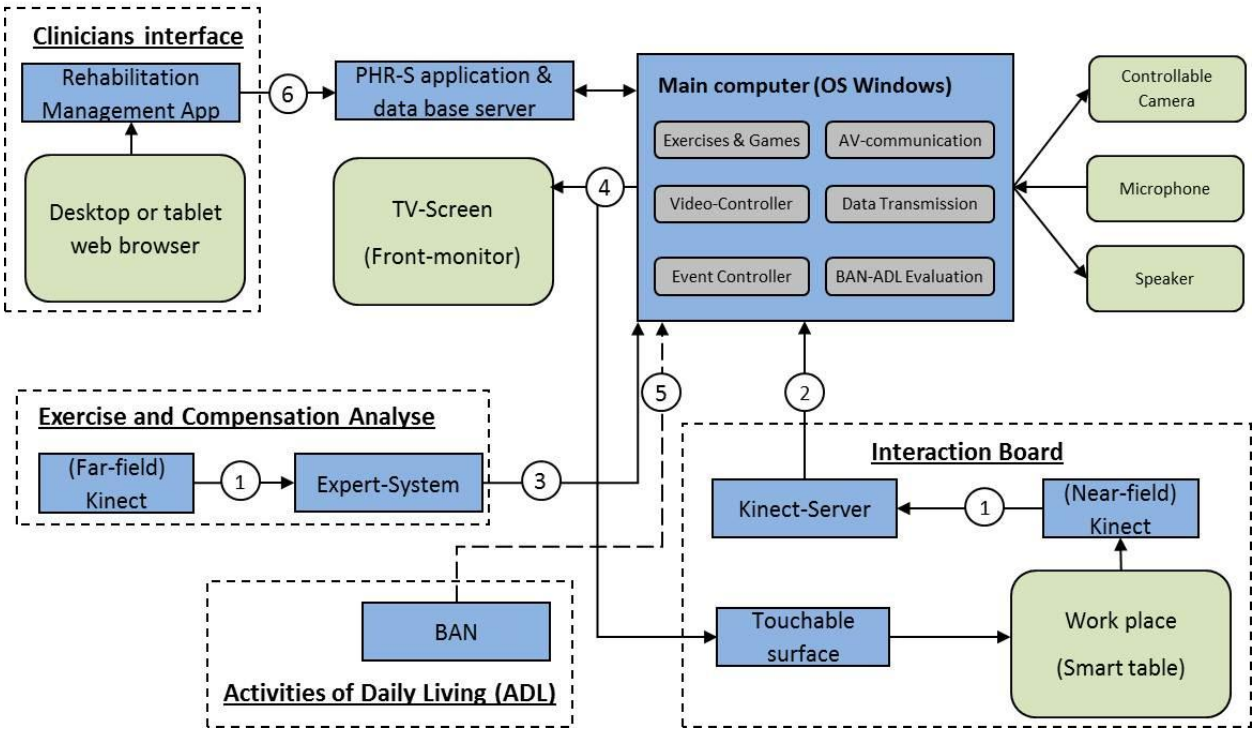

Figure 4 Data flow related to the Home Exercise scenario

With reference to the above figure, the targeted concept in this use case includes the following steps: The game handling succeeds from interactions board (projected content plus touch event) via the Kinect-Server to the "Event Controller" in the host PC. The "Event Controller" provides the interface between the HID (Human Interface Device, i.e. mouse or keyboard) and the game. The "Event Controller" transforms any Ethernet datagram into HID-event.

1.3 Activities of Daily Living (ADL)

In this use case, the home-based BAN will be used to surreptitiously gather data from the patient during activities of daily living (ADLs). This removes the bias often encountered due to patients trying harder during exercises when they know that they are being assessed and therefore provides a more accurate measure of patient effort and progress. It is therefore of vital importance that the method by which the sensors are attached is both comfortable and non intrusive to the patient and does not restrict normal

activities or movements. Ideally the BAN garments might take the form of a simple wrist strap, upper arm strap and chest band.

The home-based BAN will also contain a processing hub with data storage facility and a wireless receiver. The BAN sensors will at this stage have been re-programmed by the PC software to operate at a lower acquisition rate to prolong battery life. The hub will process the sensor data in real-time and perform data compression to reduce data storage requirements (thus helping to extend the BAN operational lifetime).

Data will be gathered by the BAN over a fixed period (battery life dependant) and at the end of a session this data will be downloaded from the hub to a PC through some form of docking station. The data will then be analysed to look for the classifying, characteristic patterns that are associated with particular movements or operations (as defined in the clinical assessment phase and daily PC gaming phase).

Other patient activities not previously defined by data patterns may also be inferred, such as inactivity, lying down, sit-to-stand, stand-to-sit, and so on. Once these activities have been identified within the BAN data, they will be presented to the patient in a meaningful format and also stored on the PHR for later analysis by clinicians. Presentation formats might for example simply convey information such as the patient performed 20 reach-and-grasp tasks during the monitoring period which revealed that the time to complete this task increased over the course of the day by 15% or the patient was inactive for 3 hours and 20 minutes during the monitoring period.

1.3.1 General design guidelines

- BAN easy to put on and remains in place
- Comfortable to wear, lightweight and not restricting normal body movement
- Extended energy autonomy of the BAN
- Docking station for downloading data from the BAN and for recharging batteries
- USB connector for data transfer to host PC
- Bluetooth for data transfer
- Docking station for downloading data from the BAN and for recharging batteries

1.3.2 ICT Infrastructure involved

The building blocks of the infrastructure involved in the realization of this use case are depicted in the following figure.

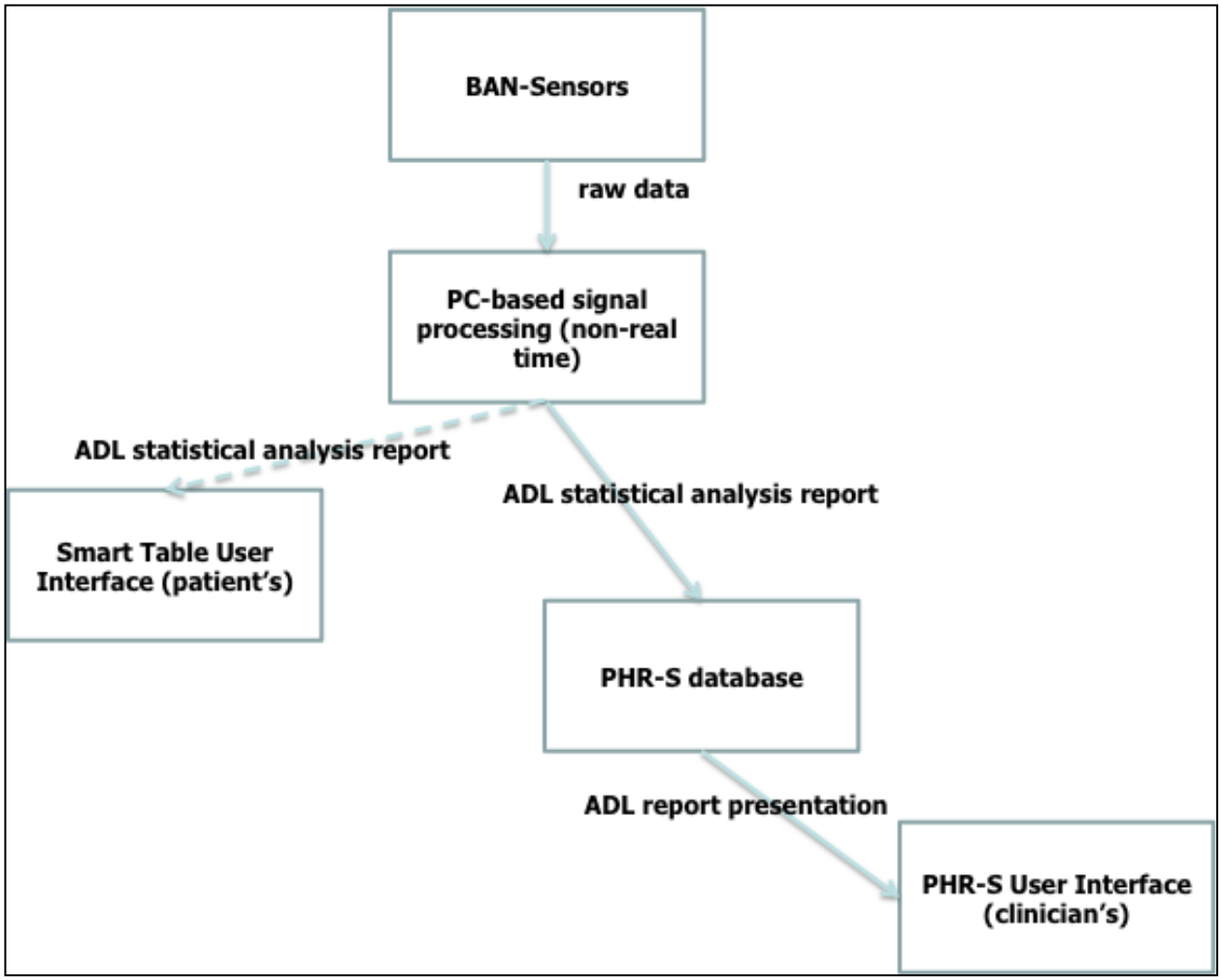

Figure 5: Infrastructure necessary for activities of daily living use case[2]

1.3.3 Data flow related to ADL scenario

The following data flow corresponds to the ADL monitoring scenario as depicted in Figure 6:

1. Raw sensor data from gyroscopes and accelerometers that is collected while the patients wears the BAN during the day.
2. Upload of classified movement data and ADL activities to PHR.
3. Presentation of daily ADL summary to patient and clinician.

[2] Arrows or boxes in dashed line indicate optionality at the time of preparation of this document

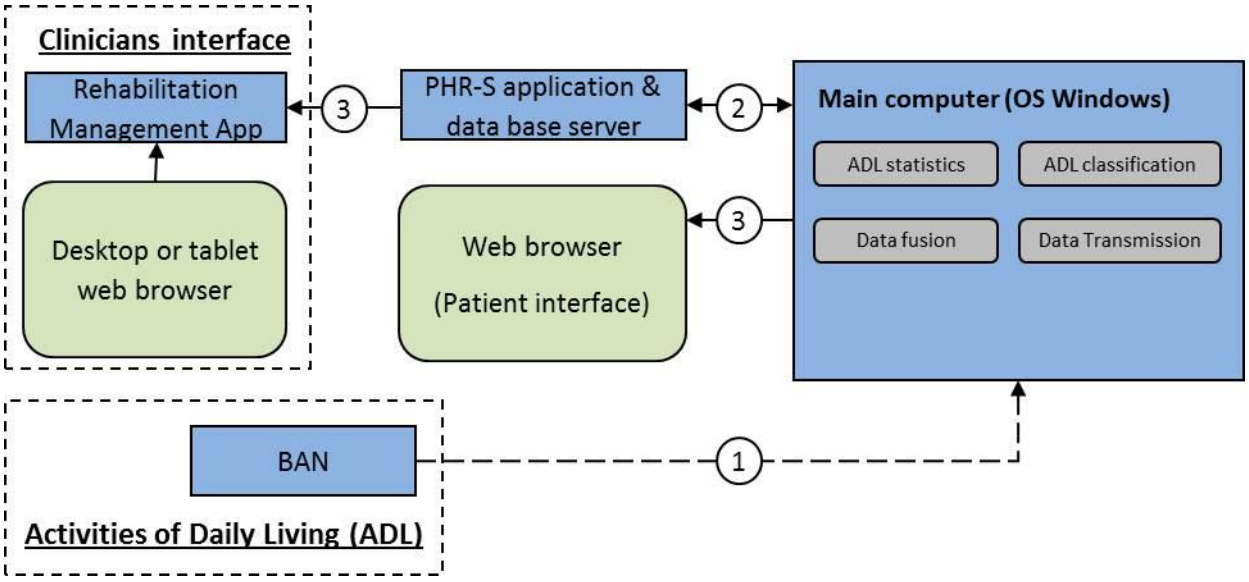

Figure 6: Data flow related to the ADL monitoring scenario

2 Functional requirements of StrokeBack ICT components

2.1.1 Rehabilitation Management Application

Version	Date	Changes	Responsible Partner
0.1	September, 2012	Initial version	ICOM

General Description	This application also provides functionality related to the clinical assessment of the patient during the execution of supervised tests e.g. the Wolf Motor Function Test (WMFT), the Stroke Specific – Quality of Life Scale (SS-QOL) and the Barthel Index in the clinical environment. The clinician should also be given the ability to re-rate the patient's performance in subsequent visits. It also enables physicians to set up and monitor detailed rehabilitation plans and related activities for their patients. Finally, It serves as a front end for getting access to the information collected by the BAN and associated statistical analysis reports.
Physical Actors User characteristics	Physicians Therapists Patient (only for viewing)
Functional Requirements	See in the sub-sections below detailed description
Non-functional requirements	See in the sub-sections below detailed description

Data Requirements	BAN streams (21 streams coming from three kinematic sensor nodes (each node = 3 axis accelerometer and 3 axis gyroscope), 2 EMG sensors and ECG sensor Motion Capture System stream WMFT scoring form (filled in manually by the clinician) Barthel Index (BI) questionnaire (filled in manually by the clinician) Stroke Specific Quality of Life Scale (SS-QoL) questionnaire (filled in manually by the clinician) (optional) Energy expenditure calculated from EMG data (optional) Metabolic rate calculated from ECG data

2.1.1.1 View Patient List

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The patient list consists of the patients' names the clinician has taken care of in the past up until present. Every line in the list represents a single patient. The list's columns include some basic information; the patient's name, birth date, father name and the is Active column. The last column is checked in case the patient is still in Training. If the patient is not active, the Planning Tool option from the menu will remain inactive until he is back in Training mode.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It shall allow the clinician to view a table containing a list of his patients' names, father names, birth dates and is Active.
Non-functional requirements	
Data Requirements	Patient name, Father name, Date of birth, is Active.

2.1.1.2 Search Patient

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	A clinician usually has to take care of a large number of patients concurrently. Therefore finding a patient from the patient list is not an easy task. In case the

	clinician knows the name and/or father name of the patient he is looking for, he can submit only the first or even both in the search form. The Search Patient form is shown together with the Patient List.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It shall allow the clinician to insert the patient's name. It shall allow the clinician to insert the patient's father name. It will provide results when submitting either the patient's name or father name.
Non-functional requirements	
Data Requirements	The list of the patients' names and father names.

2.1.1.3 View Reminders

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The Reminders appear as a flashing link above the Search Patient form. When the clinician clicks on the link he views the list of Video Conferences for today, the list of upcoming Visits and the list of Questionnaires he has to fill in. The Reminder for a Questionnaire will appear after a fixed time, based on the last time the clinician filled in the same type of questionnaire. For instance, the Questionnaire Reminder should appear three weeks after the last questionnaire was filled in, and the Reminder should flash for the whole week until it's finally filled in. The Reminders for Video Conferences and Visits will appear in a fixed date arranged by the clinician and the patient.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to view the upcoming Visits, Questionnaires he has to fill in and Video Conferences to attend. It will allow the clinician to view the Questionnaire type he has to fill in. It will allow the clinician to view the patient names to whom the Questionnaires, the Video Conferences and upcoming Visits concern. It will allow the clinician to view the time that the upcoming Visits and Video Conferences will take place.
Non-functional requirements	
Data Requirements	The list of Questionnaires and the time period after which the questionnaire has

	to be filled in, upcoming Visits, Video Conferences and the corresponding dates and patient names

2.1.1.4 View Patient Personal Details

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	When the clinician selects a patient from the patient list the person's details will appear on the screen. The patient's details are always visible, besides the screens where there is no patient selected like the login screen and the patient's list screen. The patient's personal details will include social information such as his full name, date of birth, address and phone number, as well as information on his diagnosis and his training period.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to view the personal details of the patient.
Non-functional requirements	
Data Requirements	Patient Name, Date of Birth, Main Diagnosis, Father Name, Address/ phone number, email, Training Period

2.1.1.5 Fill in new Questionnaire

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The clinicians have to fill in the questionnaires on behalf of the patients. The patients execute exercises included in the Wolf Motor Function Test (WMFT) and the clinician inserts the score of each exercise. The WMFT endscore is calculated and stored persistently. Also, the clinician has to insert the patient's answers on the questions of the Stroke Specific Quality of Life (SS-QoL) and the Barthel-Index (BI). The patient's answers, scores and endscore are inserted in the database and stored persistently.
Physical Actors User characteristics	Physicians Therapists Patients

Functional Requirements	It shall allow the clinician to insert the scores of the WMFT exercises. It shall allow the clinician to insert the patient's answers on the SS-QOL. It shall allow the clinician to insert the patient's answers on the BI. It shall allow the clinician to insert the current date.
Non-functional requirements	The questionnaires will be available in multiple languages (English and German). There will be a manual providing guidelines to the clinician on how to fill in the questionnaire.
Data Requirements	The selected language, the list of exercises in the WMFT, the scores for each WMFT exercise, the questions in SS-QOL, the answers for each question in the SS-QOL, the score of each answer in the SS-QOL, the questions in the BI, the answers for each question in the BI, the score of each answer in the BI.

2.1.1.6 Overview of Assessed Questionnaire Endscores

Version	**Date**	**Changes**	**Responsible Partner**
0.1	October, 2012	Initial version	ICOM

General Description	The clinician is able to view the details of all the previously submitted Questionnaires. First, he has to select a type of Questionnaire. Then, a list with the dates that the Questionnaire has been submitted will appear, along with the endscore.
Physical Actors User characteristics	Physicians Therapists Patients
Functional Requirements	It shall allow the clinician to view the list of the Questionnaires submitted in the past, as well as the date they were submitted. It shall allow the clinician to view the endscores of all submitted Questionnaires.
Non-functional requirements	
Data Requirements	The dates that the Questionnaires were filled in, the types of the Questionnaires and the endscores.

2.1.1.7 Print Ascertainment

Version	**Date**	**Changes**	**Responsible Partner**
0.1	October, 2012	Initial version	ICOM

General Description	After the evaluation of the patient's level of impairment, the clinician and the

	patient make an agreement on the patient's training, set the goals and the objectives of the rehabilitation. The latter are included in the context of the Ascertainment. The Ascertainment is actually a document in a printable form. It is a piece of paper that both the patient and the clinician have to sign. The ascertainment will include the set of exercises the patient agrees to be trained, the goals and the objectives of the rehabilitation process. The clinician prints it out and fills it in with the schedule of the tests and exercises and it is signed as a contract between the patient and the therapist.
Physical Actors User characteristics	Physicians Therapists Patients
Functional Requirements	It will allow the clinician to print the ascertainment. It will allow the clinician and the patient to sign the ascertainment.
Non-functional requirements	The ascertainment has to be in a printable form.
Data Requirements	The ascertainment document.

2.1.1.8 Insert or Update Healthcare products

Version	**Date**	**Changes**	**Responsible Partner**
0.1	October, 2012	Initial version	ICOM

General Description	The clinician selects which products the patient is using among a list of available products. If the clinician has inserted products for the selected patient in the past, they will appear as selected on the list. The clinician can update the list by unselecting some products in case the patient is no longer using them or select new ones and clicking on the insert button.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to select or unselect healthcare products.
Non-functional requirements	
Data Requirements	List of products available, Health care products used in the past.

2.1.1.9 Use Planning Tool to Schedule Exercises

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	There are three types of exercises in the Planning Tool. The clinician will select which type of exercises will be executed in each session. The system should by default set 5 sessions per week and 15 sessions minimum for a training period. The clinician selects the level of difficulty of each exercise and inserts the time account, and the repetition account of the exercise. The clinician will be able to insert free text notes for the patients as well.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to select the type of exercises. It will allow the clinician to modify the number of sessions in a Training Period. It will allow the clinician to select the level of difficulty for each exercise.
Non-functional requirements	The number of sessions will be 15 by default, but could be changed by the clinician .
Data Requirements	Types of exercises, available levels of difficulty of each exercise.

2.1.1.10 View Done Exercises

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	All of the raw data collected from the body-worn wireless sensors and motion capture system as well as processed data will be stored in the PHR. When the date of an exercise has passed the exercise will move to the Done Exercises section. The Done Exercises will include the parameters extracted from the BAN data for each day.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to view the dates of the Done exercises. It will allow the clinician to view the data gathered for each date of the Training Period that has passed. It will allow the clinician to view the names of the Done exercises
Non-functional requirements	

Data Requirements	List of past dates, Exercises done on those dates, the level of difficulty of each exercise, the patient's time account, and the patient's repetition account.

2.1.1.11 View Scheduled Exercises

Version	**Date**	**Changes**	**Responsible Partner**
0.1	October, 2012	Initial version	ICOM

General Description	The clinician will see a list of the patient's upcoming exercise dates. The list will include the names of the exercises that have to be performed on each date. When the clinician selects a date, the detailed view of the day's schedule will appear in the center of the screen. He can also change the exercise plan in order to adapt to the progress of the patient.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to change or delete exercises. It will allow the clinician to view the exercises included in each date of the Training Period. It will allow the clinician to view the level of difficulty of the scheduled exercises, the suggested time account, and the suggested repetition account. It will allow the clinician to view the next dates in the Training Period of the patient.
Non-functional requirements	
Data Requirements	List of scheduled dates, Exercises to be executed in future dates, the level of difficulty of the exercises, the suggested time account, and the suggested repetition account

2.1.1.12 View Exercise List in Training Results

Version	**Date**	**Changes**	**Responsible Partner**
0.1	October, 2012	Initial version	ICOM

General Description	The Training Results are the set of exercises executed by the patient during the Training Period. As the patient continues his training schedule, new exercises and exercise dates will be added in the results. The available data will also contain the statistical outcome (reports) of the PC based signal processing tool, as stored in the PHR-S. The clinician can choose between the graphical representation of the exercise parameters or a listing of the parameter values.

Physical Actors User characteristics	Physicians Therapists Patients
Functional Requirements	It will allow the clinician to see a list of the exercise names the patient has executed during the Training Period. It will allow the clinician to view a list of the available parameters for each executed exercise. A non-graphical representation of the parameter values will be available as well.
Non-functional requirements	
Data Requirements	Names of executed exercises, Names of available parameters for each exercise.

2.1.1.13 View Graphs of Training Results

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The Training Results are also available in a graphical representation. After choosing a specific exercise from the Training Results list, as well as a parameter from the available exercise parameters, and clicking on the graph option the graph will appear on the central screen. The graph will be an image containing a line chart. The x axis of the graph will consist of the dates which the patient executed the selected exercise. Whereas the y axis will contain the corresponding parameter values. An additional option to limit the time period of the x axis will be available as well. Using this option will give focus on a smaller time period for an even more detailed view of the Training Results. The graphical representation can be extracted in a Portable Document Format (pdf) for easier storage.
Physical Actors User characteristics	Physicians Therapists Patient
Functional Requirements	It will allow the clinician to view a line graph of the exercise results. It will allow the clinician to insert a start date and an end date to limit the time frame of the graph. It will allow the clinician to save the graph in a Portable Document Format (pdf)
Non-functional requirements	
Data Requirements	Exercise name, Exercise dates, Parameter values.

2.1.1.14 View Parameter Values of Training Results

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The listing of the parameter values is an alternative representation of the Training Results. After selecting an exercise and a parameter from the Training Results list, the clinician has to select the parameter list option. Then a table will appear in the central screen, containing the exercise dates on the left column and the parameter values on the right
Physical Actors User characteristics	Physicians Therapists Patients
Functional Requirements	It will allow the clinician to view the table containing the parameter values and the corresponding dates.
Non-functional requirements	
Data Requirements	Exercise name, Exercise dates, Parameter values.

2.1.1.15 Schedule new Video Conference

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	A new videoconference date can be set up in agreement with the patient. The clinician has to insert a new date, optionally he can insert some personal notes on the date, and hit the submit button.
Physical Actors User characteristics	Physicians Therapists Patient
Functional Requirements	It will allow the clinician to insert a new videoconference date. It will allow the clinician to insert personal notes on the videoconference date.
Non-functional requirements	
Data Requirements	

2.1.1.16 Schedule new Visit

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	A new clinical visit can be set up in agreement with the patient. The clinician has to insert the date, optionally he can insert some personal notes on the date, and hit the submit button.
Physical Actors User characteristics	Physicians Therapists Patient
Functional Requirements	It will allow the clinician to insert a new visit date. It will allow the clinician to insert personal notes on the new visit.
Non-functional requirements	
Data Requirements	

2.1.1.17 Insert or Update Diagnosis

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The clinician can keep a list of the medical diagnoses made for a patient. There are three ways to insert a new Diagnosis. The first is to select the medical specialty related to the diagnosis from a drop-down-list. Every specialty is linked with a different set of diagnoses. The second way is to insert the diagnosis as a free text in a simple input without selecting a medical specialty. And lastly, the clinician can select a disease from the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD10 List), which is a medical classification list by the World Health Organization (WHO). Before submitting the diagnosis he has to insert the date the patient was first diagnosed with the illness and the name of the clinician who did it. The information whether the illness diagnosed is still active is also necessary.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to select a specialty from a drop-down-list. It will allow the clinician to select the name of the disease diagnosed from a drop-down-list.

	It will allow the clinician to insert the diagnosis in a text input in the form of free text. It will allow the clinician to select a disease from the ICD10 List. It will allow the clinician to insert the date of the first diagnosis. It will allow the clinician to insert the name of the clinician who did the diagnosis. It will allow the clinician to insert whether the illness is still active.
Non-functional requirements	
Data Requirements	Specialty List, List of diseases per specialty, list of diseases in the ICD10 List.

2.1.1.18 View Submitted Diagnoses

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The clinician can view a table listing the diagnoses related to the selected patient. Each row in the table concerns a new diagnosis and its columns include the diagnosis name, date, clinician name, status and a change button. The clinician can change a diagnosis from the list by hitting the change button.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to see a list of the diagnoses names, dates, clinician names and states. It will allow the clinician to alter a diagnosis.
Non-functional requirements	
Data Requirements	The diagnoses names, corresponding diagnoses dates and names of the doctors who diagnosed the selected patient.

2.1.1.19 View Calendar

Version	Date	Changes	Responsible Partner
0.1	October, 2012	Initial version	ICOM

General Description	The Calendar offers an overview of the clinician's schedule. It includes upcoming Visits, Video Conferences and Questionnaires. Different instance types (either a Visit, Video Conference, or Questionnaire) are represented by different colours. An instance on the Calendar is illustrated as a round, coloured dot. Clicking on

	the dot opens a small frame containing details of the instance. It is possible to limit the time period of the current view of the Calendar by inserting a starting and an end date.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to view a summary of his schedule. It will allow the clinician to view details of the instances on the Calendar. It will allow the clinician to limit the time frame of the Calendar.
Non-functional requirements	
Data Requirements	The time and dates of the upcoming Visits, Video Conferences and Questionnaires. The information on the upcoming Visits, Video Conferences and Questionnaires.

2.1.1.20 Send an Email

Version	**Date**	**Changes**	**Responsible Partner**
0.1	October, 2012	Initial version	ICOM

General Description	The clinician can communicate easily with his patients via email. The PHR system contains the electronic addresses of the patients. The clinician simply has to select a patient from the list, insert a text message and hit the submit button. The system sends the message to the electronic mail address assigned to the selected patient.
Physical Actors User characteristics	Physicians Therapists
Functional Requirements	It will allow the clinician to select a patient from the list; the recipient of the email. It will allow the clinician to write a text message.
Non-functional requirements	
Data Requirements	The email address of the selected patient.

2.1.2 PHR-S administration tool

Version	**Date**	**Changes**	**Responsible Partner**

0.1	September, 2012	Initial version	ICOM

General Description	This tool enables the IT personnel of the StrokeBack service provider to administer the system.
Physical Actors User characteristics	IT staff
Functional Requirements	• Register end users (physicians, therapists, patients, relatives) • Register equipment associated with end users • Manage PHR-S database
Non-functional requirements	None
Data Requirements	Patient's unique IDs, Equipment IDs
Interfaces	TBD.

2.1.3 Expert BAN system processing application

Version	Date	Changes	Responsible Partner
0.1	September, 2012	Initial version	SOTON

General Description	This application is responsible for the correlation and analyse of the data collected by the BAN while execution of clinical assessments. The outcome of this process is an advanced statistical analysis report about analyse results that will be fed to the PHR-S database and subsequently presented in the PHR-S web interface. An optional feature that is the integration of Emotiv EEG as well as an ECG and EMG sensors in the BAN. These are not considered critical from the clinical point of view – or even, clinically reliable, as long as the Emotiv is considered- but may provide useful insights at a research level.
Physical Actors User characteristics	Physician Therapist
Functional Requirements	Communication and configuration management of BAN Synchronisation of all sensor data Schedule of WMFT
Non-functional requirements	Ease of configuration by Physician

Data Requirements	TBD.
Interfaces	The presentation layer of this application should be integrated with the PHR-S user interface, so as for the clinician to have a common entry point for all the UI that facilitate its workflow.

2.1.4 Exercise evaluation

Version	**Date**	**Changes**	**Responsible Partner**
0.1	September, 2012	Initial version	UP

General Description	The exercise evaluation tool real-time supervision of rehabilitation exercises. It allows to record and monitor individual exercises. This training system should be individually trained / configured by the therapists for certain patient to fit the clinical requirements of stroke rehabilitation. Therefore, the system may “learn” new exercises on the fly, which means to model individual movement automatically in a way that allows the system to evaluate movements according to the modelled exercise later. .
Physical Actors User characteristics	Therapist Patient
Functional Requirements	Calculation of 3-dimensional vectors of all upper body parts Recording of complex exercises as a series of consecutive very small movements Tolerance range for movements that is configurable by the therapist according to the patient’s current state of rehabilitation and expected precision of movements
Non-functional requirements	None
Data Requirements	“Skeleton stream” data from OpenNI and Microsoft Kinect SDK
Interfaces	TBD.

2.1.5 Compensation tool

Version	**Date**	**Changes**	**Responsible Partner**
0.1	September, 2012	Initial version	UP, BBK

General Description	This tool should detect unwanted or not-allowed movements during training sessions, called compensational movements. This is especially desirable from the

	therapeutical point of view. In a real-life trainings session, normally the therapist pays attention to unintentional movements and corrects those, e.g. leaning forwards or movement of the shoulder. In StrokeBack, the monitoring systems should do this automatically. Hence, we'll investigate that need to be monitored during normal execution of exercises.
Physical Actors User characteristics	Therapist Patient
Functional Requirements	Library of compensational movements Automatic detection while monitoring upper body
Non-functional requirements	Ease of configuration means for therapists
Data Requirements	TBD.
Interfaces	TBD.

2.1.6 ADL processing application

Version	Date	Changes	Responsible Partner
0.1	September, 2012	Initial version	SOTON

General Description	This entity is responsible for analysing the data collected by the BAN nodes while the patient executes ordinary everyday activities. This entity manages filtering, processing, segmentation, compression of data originating from the sensor nodes, and, eventually, activity classification. Tentative metrics for the collected information could be intensity estimation, basic activity recognition, background activity recognition, etc. As a software module, this entity runs at the patient's home PC unit. Another option is that it runs at the PHR-S side (PHR-S application server). The latter option makes sense mainly for use by the clinician, over the web. However, the usability of additional hardware modules for on-BAN feature extraction and movement classification will be investigated. If appropriate, such modules may be integrated into the microcontrollers of the sensor nodes or be manufactured as System on Chip (SoC) or System in Package (SiP). All other processing that produces data intended for the PHR will be done by the local host PC in an offline operation. It seems feasible to investigate the following ADL: 1. Reach and retrieve object

	2. Lift cup to mouth and return to table 3. Swing arm in horizontal plane through 90° and return 4. Rotate wrist through 90° and return
Physical Actors **User characteristics**	none
Functional Requirements	Requires BAN with sensors Requires a means of transferring data to host PC
Non-functional requirements	Requires periodic charging of batteries
Data Requirements	Cannot be precise at this moment, but if we assume 30Hz collection rate (to synchronise with Kinects) and that a BAN has 3 sensor nodes where each node has 8 16-bit data streams, then over 10 hour period this equates to 50,625 kBytes of raw data storage. However, the BAN will also perform feature extraction in real-time though we do not know yet how many features will be collected. A realistic figure might be a total storage capacity of 60 MBytes per day.
Interfaces	USB for charging and data transfer Bluetooth (or other communication means) for transmitting calibration data to BAN during game phase.

2.1.7 ADL presentation

Version	Date	Changes	Responsible Partner
0.1	September, 2012	Initial version	MEYTEC + ICOM

General Description	This entity comprises the presentation layer of the applications that analyses the data related to ADL. Different options may be realized: for patients (simple) and for clinicians (advanced). The former will be designed for the home station that will be used by the patient (MEYTEC), while the later will be designed as an integrated part of the clinician's web interface (ICOM). At the time of preparation of this version of the design guidelines, the ADL presentation to the patient is considered as optional. The functional requirements related to the presentation to the clinicians are summarized in paragraphs 2.1.1.122.1.1.13 and 2.1.1.14
Physical Actors User characteristics	Physicians and therapists (web user interface) Patient (home station user interface)
Functional	Presentation must be adapted to corresponding user interface, e.g. for a tablet or a TV-monitor.

Requirements	
Non-functional requirements	Keep it very simple, no details.
Data Requirements	TBD.
Interfaces	TBD.

2.1.8 PC-based Serious Games

Version	Date	Changes	Responsible Partner
0.1	September, 2012	Initial version	RFSAT, UP, PE

General Description	To keep also the motivation of the patient high while exercising, the exercises are to be combined with small games. The gaming engine will be loosely coupled to different exercises, which means the controlling movements can be individually set to the patient's therapeutic needs. Of utmost importance is the user interface of this application, as it should be attractive and generate meaningful feedback to the subject, while performing the exercises.
Physical Actors User characteristics	Therapist Patient
Functional Requirements	Control of games via exercises that will be collected as events by an event observer pattern
Non-functional requirements	Look and feel must be attractive for stroke patients Consider potential handicaps, such as aphasia
Data Requirements	Statistics and configuration data, e.g. results, levels etc. need to be stored in the PHR.
Interfaces	TBD.

2.2 StrokeBack architecture constraints

2.2.1 Body Area Network

- *Hardware*:
    - At least 3 sensors will be necessary to monitor the activities of one arm and Activities of Daily Living (ADL). The first sensor will be attached to the wrist, the second one is attached to the upper arm and the third sensor should be located at the sternum.

- The sensor nodes will have the following basic components:
  - Microcontroller: MSP430 family from Texas Instruments on Shimmer nodes. Will be substituted by Crypto-microcontroller from IHP at StrokeBack sensor nodes.
  - 3-axis accelerator sensor
  - Dual-axis gyroscope sensor
  - Exchangeable communication module connected via SPI. Several candidates will be investigated, e.g. ZigBee and Bluetooth Low Energy (BT-LE)
  - Integrated small antenna
  - Micro SD-Card Slot
  - USB connector for debugging purposes. It may also be used for charging depending on battery pack and required energy supply.
  - Battery pack
- All motion capturing and classification means will be based on data from accelerometers and gyroscopes. We will prevent from applying magnetometers on the node as another data source, because of their easy interference with and disturbance by any kinds of magnetic or metallic source, e.g. wheelchairs.
- Each sensor will be able of both storing all data locally and sending data directly to the Gateway component. There is no need to establish permanent online connectivity from the sensor to the Gateway. From therapeutical point of view, it is merely required to gather statistics about ADL on daily basis, i.e. the patient's ADL need to be available on the following day in the PHR.
- Further sensor nodes with EMG and ECG facilities that may be used for the clinical assessment and the WMFT will be investigated. However, the necessity and clinical relevance of ECG and EMG for rehabilitation of stroke patients is yet object of research and not a key objective of StrokeBack.
- Communication facilities on the sensor nodes are to be used to synchronise all nodes and timestamps while recording data throughout the day.
- The necessity of having additional pre-classification hardware modules on the node will be investigated. Such hardware module should accelerate the process of analysing the ADL on the nodes while reducing the amount of stored data at the same time. If appropriate, it may be integrated into the IHP-crypto microcontroller or be manufactured as System on Chip (SoC) or System in Package (SiP).

- Software:
  - For current implementations on the shimmer hardware, the Shimmer Software Development Kit (SDK) is used. It is based on the TinyOS operating system for sensor nodes.
  - The software that is used on the final hardware will be selected when the StrokeBack sensor nodes have been designed.
- Gateway to PHR:

- The Clinical or Home Gateway will be used to connect the BAN to the PHR. It will therefore be equipped with a small receiver, most probably as USB stick, and a small program that can receive data from the sensor nodes. It will also host the application that classifies sensor data to ADL and mediates between the BAN and the RHR repository. See also Home based Processing Hub in next section.

2.2.2 Home based Processing Hub

This processing hub is a powerful PC using windows as operating system. It host all offline applications, e.g. exercise evaluation, compensation analyse, ADL classification etc., and mediates data uploads and updates between the StrokeBack system at the clinics/patients home and the PHR.

2.2.3 Home-based interaction board

The "interaction board" allows the patient to interact with real world objects following instructions coming from a horizontally integrated monitor or projections at the surface of the working desk. This should enable to automatically monitor classic training methods from occupational therapy such as manipulation and placement of different objects. It will be using the Kinect in near field mode.

It further deals with fine-granular tracking of hand movements and gesture recognition for a single hand. In particular, to clench a fist, to open and close the hand as well as extension / flexion of the wrist should be observed. This setting will be investigated as an extended rehabilitation tool. None of the currently available Service Development Kits (SDK's) for the Kinect camera allow for fine-grained tracking of hand movements or finger tracking in general.

Details about this interaction board can be found in D6.1.

2.2.4 Equipment for ECG, EMG and EEG

- EEG measuring device

Measuring EEG data from stroke patients in a clinical environment is common practise but currently applied for research purposes only. It is not part of a standard therapy schedule. Moreover, clinically relevant, off the shelf EEG recordings are costly, time-consuming and mostly need to be handled by trained staff. However, we plan investigating the synchronisation of exercise and movement data with EEG data. Therefore we'll investigate the usage of a mobile EEG headset from emotive (www.emotiv.com). It is easy to use and may allow for applying it also in home scenarios. During the StrokeBack project, this headset will only be used for the clinical assessment due to availability of a medical staff. Data will most probably be transferred to the Gateway component together with results from clinical assessment.

- ECG and EMG devices

Currently, we will rely on the ECG and EMG devices from shimmer to investigate their relevance and need in the StrokeBack system. From clinical point of view, we should concentrate on the rahbilitation measures first.

2.2.5 Equipment for Wolf Motor Function Test

A laminated template (with object positioning, placement and target lines)

- Stopwatch

- A box (23cm H / 35 cm L / 26 cm W)
- Weights – 1lb wrist weight with Velcro strap; 3 lb weight
- 12oz unopened soft drink can
- 7-inch pencil
- 2-inch paper clip
- 3X5 inch playing cards
- 3x checkers size:
- Standard Yale Key and lock mounted at 16cm height on a board, tumblers of the lock set to allow 1800 arc, with 900 of that arc on either side of midline
- Small dishtowel – approx. size: 57cm x 41 cm

2.2.6 Rehabilitation Excercises and Games

A high level architecture of the gaming system is depicted in Figure 7. The gaming system contains two core components: the game server and the game client. The game server is deployed on the classical HTTP + Java application server (e.g. Apache HTTP + Tomcat servers are sufficient) allowing games to be played using a standard HTTP4/5 compatible WEB browser (Chrome, IE9+, Firefox etc.). The games are loaded in a form of a WEB page with Java scripted game functionalities. Using such an approach games can be easily packed into deployable packages to be handled by PHR.

Two deployment approached can be considered:

1. Top one in Figure 7: simplifying client-side hardware requirements to the minimum. The only device required at patient's home is the Kinect server. Apart from it the game can be executed on any home device with WEB browser (TV, computer, Smartphone etc) and image displayed on any visualisation device (TV, monitor, projector). In this scenario the game server resides on the remote system alongside the PHR. The drawback of such a solution is that any interruption of the network connectivity may cause breaks in the execution of the game as well as continuity of the progress monitoring.
2. Bottom diagram in Figure 7: a network-independent solution, where game server is deployed locally at patient home. In such a case there is also a need for a simplified application gateway too, which would manage the offline operation of the gaming server and its interaction with PHR. However, in this case any interruption of network connectivity would NOT cause any effect on the execution of the game, ability to store progress and movement data. It also allows for local caching of the games. In principle Smart TV or Smartphones should still be powerful enough to handle the necessary computational load. Nevertheless a dedicated embedded computer would be a more suitable solution.

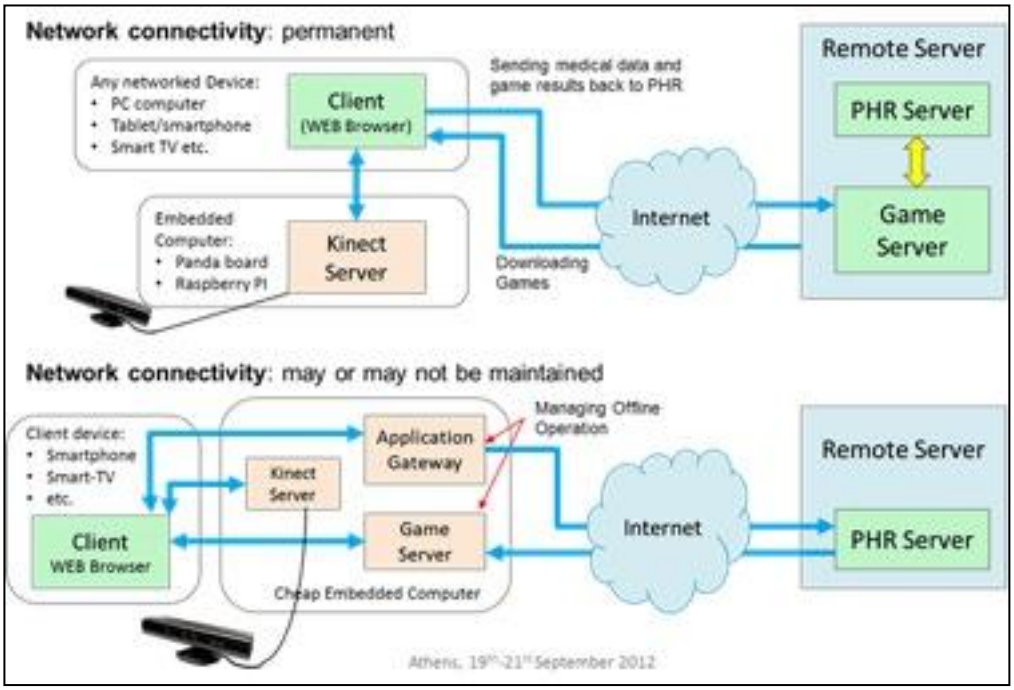

Figure 7: Gaming system architecture

2.2.7 PHR-S

For the PHR-S server, the following architectural constraints apply:

Hardware requirements: Intel Pentium, 4 CPU (4 X 3 GHz), RAM 4GB, 80G Hard Disk Partitioning in 40G, 40G, (Preferred with SATA Connectors)

- Operating System: LINUX Operating system, one of the following: Oracle Enterprise Linux 4 Update 7, Oracle Enterprise Linux 5 Update 2, Red Hat Enterprise Linux 4 Update 7, Red Hat Enterprise Linux 5 Update 2, SUSE Linux Enterprise Server 10 SP2, SUSE Linux Enterprise Server 11
- Software requirements: J2SE 5.0, Java SE 6, Glassfish Application Server v2, Apache + PHP server, MySQL db server, Oracle Express DB Server, VLC Media player (latest edition)

For a tablet running PHA, the following architectural constraints apply:

- Software development environment: Eclipse Helios v3.6 IDE with Android SDK v.1.6
- Programming language: JAVA

References

[1] Mahoney, F.I.: Functional evaluation: the Barthel index, Maryland state medical journal, vol. 14, pp. 61-65, 1965.

[2] Williams, L.S., Weinberger, M., Harris, L.E., Clark, D.O., Biller, J.: Development of a stroke-specific quality of life scale, Stroke, vol. 30(7), pp. 1362-1369, 1999.

3 Appendix I: Risk Assessment Table

No	WP	TOPIC/TARGET	RISK	PROBABILITY			IMPACT SEVERITY			RISK CLASS
				L	M	H	L	M	H	
1	2	Operating system of the host PC	Different OS requirements imposed by the components running at the host PC make it difficult to adopt a common solution		M			M		II
2	2	Complexity of the ICT infrastructure for novice end users	The ICT infrastructure of the StrokeBack system that realized the Home Exercise use case is composed of several discrete components that make the overall experience of using the system rather complicated			H		M		III

4 Appendix II: Risk Management Audit Log

No.	Risk	Participants involved	Potential Mitigation Actions
1	Different OS requirements imposed by the components running at the host PC make it difficult to adopt a common solution	**MEYTEC, RFSAT,**	
2	The ICT infrastructure of the StrokeBack system that realized the Home Exercise use case is composed of several discrete components that make the overall experience of using the system rather complicated	**All**	