

PAMAP

Deliverable: D6.5

Issue 0.1

Report on PAMAP Clinical Trials

		Name (company)	Date
Approved	Task T6.5 Leader	Nathalie Ville (CIC-IT)	30.06.2012
	Hierarchical responsible	François Carré (CIC-IT)	30.06.2012
		Laetitia Fradet (UTC)	30.06.2012
Verified	WP6 Leader	Ilias Lamprinos	30.06.2012
Released	Coordinator	Didier Stricker (DFKI)	30.06.2012

Dissemination level: PU

PU (Public); **PP** (Restricted to other programme participants); **RE** (restricted to a group specified by the consortium); **CO** (confidential only for members the consortium)

Document Status: final



	A AT 2000 4 4 (2
Project EU reference:	AAL-2008-1-162
Project acronym:	PAMAP
Project Title:	Physical Activity Monitoring for Ageing People
Work package	WP6: System Integration and Trials
Task	T 6.5: Clinical Trials
Deliverable number:	D6.5
Document title:	PAMAP Clinical Trials
Document type (PU, INT, RE)	PU
Version:	1.0
Date:	30/06/2012
Author(s):	Nathalie Ville (CIC-IT), Laetitia Fradet (UTC)
Contributors list:	Gabriele Bleser (DFKI), Ilias Lamprinos (ICOM), Attila Reiss (DFKI)



Table of Contents

E	xecut	tive Summary	6
1	Trie	als Preparation	7
	1.1	Time-line	7
	1.2	Selecting trials population	7
	1.3	Selecting physical strength exercises	8
2	Poi	nulation	10
-			
	2.1	Subjects inclusion criteria	10
	2.2	Recruitment areas	10
	2.3	Main features in each group	10
	2.3	3.1 Healthy subjects	10
	2.3	3.2 Patients with cardiovascular disease	11
	2.3	3.3 Patients with functional limitation	12
3	PA	MAP clinical trials description	13
	3.1	At hospital	13
	3.1	1.1 Time-line	13
	3.1	1.2 Experimental set-up	14
	3.1	1.3 Protocol	17
	3.1	1.4 Measured and collected data	22
	3.2	At home	22
	3.2	2.1 Time-line	22
	3.2	2.2 Experimental set-up	23
	3.2	2.3 Experimental procedure	24
	3.2	2.4 Measured and collected data	29
4	Сог	nclusion	31
	4.1	Global subjects feelings	31
	4.1	1.1 At hospital	32
	4.1	1.2 At home	33
	4.2	Data treatment	35
5	ΔΡ	PENDIX	20
9			

Table of Figures

Figure 1: PAMAP prototype used for strength session	14
Figure 2: Sensors based on a specific body suit using velcros.	15
Figure 3: Three of the 8 Vicon cameras around the subject	15
Figure 4: Screen illustrating the movement data sent by PAMAP sensors	16
Figure 5: Welcome on the virtual trainer (TV screen): the subject can choose the session of exercise related to	
his(her) group, using remote control.	16
Figure 6: "Gold standard" recording under human supervision before PAMAP prototype use	17
Figure 7: Patient looking at the PAMAP tutorial on TV screen	18
Figure 8: Calibration of PAMAP prototype: the patient follows TV instructions	19
Figure 9: Puppet during calibration of PAMAP system.	19
Figure 10: Patient performing her session, only using TV instructions and feed-back	20
Figure 11: Message from the PAMAP prototype related to a wrong movement	21
Figure 12: Message from PAMAP prototype related to encouragement	21
Figure 13: Resumed feed-back related to the quality of the movements performed during the semi-automatic	
mode	22
Figure 14: Indicative screenshots of the TV interface of the PAMAP EHR	23
Figure 15: Print screen from the web based user interface of the PAMAP EHR menu illustrating anthropometric	data
menu	24
Figure 16: Example of a physical activity weekly planning, daily defined, in one subject	25
Figure 17: Example of a survey directly completed on the EHR and the associated report presented to the clinicia	an.
	25
Figure 18: Upper body and torso sensors	25
Figure 19: Upper and lower limbs sensors	26
Figure 20: Mobile unit used with the touch screen	26
Figure 21: Icons appearing after having entered in the activity monitoring software, on the mobile unit	27
Figure 22: Summary of the recognized activities performed by a PAMAP subject. The icons in the top left corner	(A,
C and H) are indicating that the 3 IMUs are working properly (green colour). The patient's current heart rate is	
shown below these icons, 81 beat/min ⁻¹ in the example	27
Figure 23: Mobile unit in its pocket, worn at the belt	28
Figure 24: Instead of completing a paper physical activity notebook, the subject can label his (her) activities usir	ng
the mobile unit, after being entered in one of the main menus (Sport activities etc.)	28
Figure 25: PAMAP measurements overview	29
Figure 26: Example of a pdf report related to PAMAP measurements	30

Table of Tables

Table 1: Main anthropometric data in healthy subjects group. Data are expressed by mean ± SD (min-max)11
Table 2: Main anthropometric data in cardiovascular patients group. Data are expressed by mean ± SD (min-max).
Table 3: Main anthropometric data in functionally disabled patients group. Data are expressed by mean ± SD (min-
max)
Table 4: Free comments/suggestions given by the subjects in the questionnaire regarding the PAMAP system
evaluation (direct translation from the French answers). Categories: H Healthy subject, C and F, cardiac and
functional patient, respectively
Table 5: Motive related to fitness. Prevalence and strength of this motive in the whole group and in separated
groups. Results are expressed by the number of subjects and the related percentage
Table 6: Motive related to Appearance. Prevalence and strength of this motive in the whole group and in separated
groups. Results are expressed by the number of subjects and the related percentage
Table 7: Motive related to Competence/Challenge. Prevalence and strength of this motive in the whole group and
in separated groups. Results are expressed by the number of subjects and the related percentage
Table 8: Motive related to Social. Prevalence and strength of this motive in the whole group and in separated
groups. Results are expressed by the number of subjects and the related percentage
Table 9: Motive related to Enjoyment. Prevalence and strength of this motive in the whole group and in separated
groups. Results are expressed by the number of subjects and the related percentage

EXECUTIVE SUMMARY

The PAMAP project develops a system that enables an accurate monitoring and supervision of physical activities in aging people. Currently, PAMAP system has two main forms: first a prototype dedicated to daily and aerobic activities (based on three IMU sensors and a heart rate monitor), and second, a prototype dedicated to specific strength training (based on ten IMU sensors). PAMAP system allows not only activity monitoring but also Electronic Health Record (EHR) consulting, and strength exercises session's supervision, as could do a personal coach.

Both PAMAP prototypes have been tested on healthy and pathological aging people. In this aim, the clinical trials have been conducted in two independent phases: at hospital with PAMAP system used as a personal coach supervising a strength training session, and movements monitoring, and at subject's home during real daily life with daily and aerobic activities monitoring and EHR consulting.

This deliverable describes the main specificities and conduct of these clinical trials (respectively during hospital and home phases), and identifies some limitations and improvements to the prototype.

Chapter 1 will summarize trials preparation, on a scientific and administrative point of view. Chapter 1.1 will briefly describe the time-line, whereas Chapters 1.2 and 1.3 will specifically talk about selecting trials populations and physical strength exercises.

Chapter 2 will be related to the aging people population participating to these clinical trials. More specifically, Chapter 2.1 will address the inclusion conduct of the 30 participants. In Chapter 2.2, the main features in each of the 3 groups (respectively composed of healthy subjects, cardiovascular patients and functionally limited patients) will be developed.

Then, in Chapter 3, both phases of the clinical trials will be described, including their conduct, data recording, and also some patients', researchers' and clinicians' comments and suggestions. More specifically, Chapter 3.1 will address hospital phase and Chapter 3.2 home phase.

Lastly Chapter 4 concludes the report, summarizing initial qualitative results and indicating, how the data will be treated.

We thank the physicians who have helped us for these trials: Pr I. Bonan, Dr. S. Dulong, Dr F. Paillard, Pr. P. Rochcongar, and all the subjects who participated to the clinical trials.

1.1 Time-line

In France, clinical trials realization needs various agreements from national and local authorities. Some surveys and files must be accurately detailed and completed, with a special attention in regards of healthy volunteers. Thus, such preparation began from 2010 January to few weeks before the start of the clinical trials, in 2011 November. Several stages were achieved successfully:

- From 2010 January to 2011 May, numerous meetings, discussions and file shuttles within scientific partners (CIC-IT, Pontchaillou hospital, and all other European partners) in order to define the methodology of the clinical trials (literature review, inclusion and exclusion criteria for the volunteers recruitment, time-line of the trials, method including movements monitoring and EHR use¹, selecting the strength exercises that should be performed during the trials, measurements...). This shared work resulted in an accurate protocol.
- From 2011 January to July, drafting then submission by the CIC-IT to a French local Ethics Committee of a heavy file including this protocol with a short literature review, the aim of the clinical trials, the inclusion and exclusion subjects criteria, the methods including an accurate description of PAMAP prototype and CE agreements, measurements, statistical analysis, possible adverse events, and annexes containing information form, information consent, case report forms and activity notebooks. The local ethics committee sent its official agreement to the CIC-IT in 2011 October after few shuttles (*cf.* Appendix 1). Healthy subjects and patients could be officially recruited from this date.
- From 2011 June to July: submission of a similar file including a lot of technical description of PAMAP prototype including Web-based EHR to a national authority (AFSSAPS, dedicated to health security). After only one short shuttle in order to answer to few questions, the agreement was obtained in 2011 July (*cf.* Appendix 2).

1.2 Selecting trials population

During these meetings and discussions, from 2010 January to 2011 May, consideration was partly centered on which population PAMAP project should focus. In regard to the AAL call, people over 60 years old should enter the study. All partners agreed to study people representative of the European aging general population. Then, the first aim was to test the PAMAP prototype with people showing current chronic diseases and for whom a regular physical practice was possible and highly recommended for maintaining health and prevent disease complications². Cardiovascular patients and patients showing a functional limitation were then focused. At the middle of the project, after the expertise meeting in Kaiserslautern in 2010 December, in order to follow the European experts recommendations according to which PAMAP should also interest healthy aging people, a third group of subjects has been added in the protocol file, constituted of healthy and physically active subjects.

From 2011 April to 2012 February, numerous meetings and discussions were organized

¹ 2010 was partly used to improve EHR content and appearance, so that its use could be described to the Ethics Committee.

² Such topic corresponds to secondary or third prevention areas, depending on the definition of the WHO or scientific societies.

between the CIC-IT and Pontchaillou hospital services, and also sports associations mainly focused on retired persons or patients, in Rennes and suburbs. The aim was to communicate about PAMAP project and promote volunteers recruitment to complete the clinical trials.

After individual meetings with each subject, inclusion visits performed by the CIC-IT physician, and signed informed consents by subjects and physician (Dr F. Carré), 30 subjects have been definitively included. However 3 more at least should have replaced some ones if necessary for hospital trials, in case of illness or other problem.

According to French laws, patients could not receive financial reward whereas healthy subjects must have one after completion of the trials, in the amount suggested by the CIC-IT was agreed on with the Ethics Committee ($200 \in$). This amount was chosen in regards to other clinical trials practiced in the hospital.

Still in agreement with French laws, all subjects were reported on a national register listing the volunteers to clinical trials. They could not participate in another protocol over the same period. Moreover, during the clinical trials, any adverse event linked or not to the protocol, should have been declared by the CIC-IT to the French health authority (AFSSAPS) according to a strict protocol, clearly described in the Ethics Committee file. Clinical trials were performed under Dr F. Carré medical supervision.

1.3 Selecting physical strength exercises

From 2010 October to 2011 March, CIC-IT was partly centered on which strength exercises PAMAP project should focus to test the prototype during a strength physical training session. Many discussions have been lead with UTC and DFKI, partly related to the constraints linked to the position of the sensors on the body. Some books specialized on exercise recommendations in ageing and/or population with a disease (some of them showing numerous strength training exercises) have also been used in order to select movements, sets, and repetitions usually performed whatever the country, and not only in Pontchaillou hospital³. Given the strong experience and knowledge of the CIC-IT in physical training with patients with cardiovascular disease or functional limitation and with aging people, a sufficient panel of usual exercises could have been selected, without even knowing individual patients to be recruited. All the selected exercises could be adapted to specific patient's limitations if needed (*cf.* Appendix 3). Moreover, few physicians from Pontchaillou hospital, involved in functional and cardiovascular rehabilitation programs, validated this exercises panel as convenient in regards to the diseases and the aim of our clinical trials.

From 2011 March to April, CIC-IT members have performed all these exercises in order to take pictures and videos of the "gold standard" movements, as the patient should perform alone. All exercises have been labeled in order for all partners to use the same label when exchanging about the exercises (*cf.* Appendix 4).

³ ELeutholtz B.C. & Ripoll I. Exercise and disease management, CRC Press, 2nd Ed., 2011; Durstine JL et al. ACSM's exercise management for persons with chronic diseases and disabilities. Human Kinetics, 3rd edition, 439pages, 2009; ACSM's Resource Manual for guidelines for exercise testing and prescription. Lippincott Williams & Wilkins, 6th edition, 868 pages, 2010; Nelson ME, Rejeski WJ, Blair SN, Duncan PW, Judge JO, King AC, Macera CA & Castaneda- Sceppa C. Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. Med. Sci. Sports Exerc., 39(8) : 1435–45, 2007; Craig C. Pilates avec le ballon. Editions Exclusif, 175 pages, 2006; Gillies E. Swiss ball. Edition Marabout (Hachette Livre), 159 pages, 2008; Bimbi-Dresp M. La méthode Pilates. Pour vous détendre et améliorer votre physique. Editions France Loisirs, 176 pages, 2007; K.A. Van Norman. Exercise and wellness for older adults. Practical programmes strategies. Human Kinetics2nd ed., 165 pages, 2010; de Gasquet B. Abdominaux : arrêtez le massacre ! Edition Marabout (Hachette Livre), 195 pages, 2009

Then from 2011 May to December, all pictures and videos have been included by DFKI in the PAMAP software in order to perform the hospital trial. Moreover, a multimedia tutorial on the usage of the system as well as on general good practice of physical activity has been developed by UTC and integrated into the PAMAP software.

2.1 Subjects inclusion criteria

As a reminder, the clinical trials were conducted in order to test the feasibility and the use of the PAMAP system in ageing people, for whom a regular and moderate physical activity is recommended in order to maintain or improve their health status. According to the European expertise at the middle of the PAMAP project, in a secondary aim, the motivating factors of the subjects and their feelings related to the impact of PAMAP use on their motivation and compliance toward physical practice were also investigated. It was then chosen to investigate subjects with various however representative health statuses, physical abilities and limitations. For that purpose, 3 groups of subjects more than 60 years old were investigated: healthy subjects (n=10), cardiovascular patients (n=10), and patients with a functional limitation (n=10).

2.2 Recruitment areas

Thirty voluntary subjects entered then completed the study. Healthy subjects and patients were mainly recruited in sports associations for retired individuals and fitness centers (n=20), in Rennes center town and suburbs (France), after a research engineer from the CIC-IT had presented PAMAP system and clinical trials protocol, in each of these sports facilities.

Otherwise, in the cardiac patients group, 3 patients have beneficiated from a regular followup in Pontchaillou hospital (Cardiovascular Prevention Unity, supervised by Dr. F. Paillard) and addressed to the CIC-IT for participating to PAMAP project, as were 4 patients classified in the functionally limited patients group (Functional Rehabilitation Unity, supervised by Pr. I. Bonan).

2.3 Main features in each group

All subjects were physically active and involved in various sports and physical activities:

- walking (n=22),
- gymnastics (n=16)
- *strength training (n=9),
- cycling (n=8),
- running (n=7),
- ballroom dancing (n=6),
- tennis (n=3),
- table tennis (n=3),
- nordic walking (n=3),
- horse riding (n=1),
- volley-ball (n=1),
- water aerobics (n=1),

Some of these activities (bold font) were sometimes performed in fitness centers including group lessons (aerobic...) and individual strength training using machines.

2.3.1 *Healthy subjects*

The healthy subjects group was composed of 7 women and 3 men. Their anthropometric data are shown in Table 1. They did not show any disease during their inclusion visit and their body mass index was considered as in the normal limits according to the World Health

- tinkering (n=2),
- gardening (n=1).

Organization (WHO)4.

Age (yrs)	Weight (kg)	Height (cm)	2)	Body Mass Index (kg.m ⁻
67.2 ± 5.1	61.0 ± 10.7	161.6 ± 6.6		23.2 ± 2.2
(61-76)	(49-85)	(156-178)		(19.9-26.8)

Table 1: Main anthropometric data in healthy subjects group. Data are expressed by mean \pm SD (min-max).

These subjects were mainly practising weekly the following physical activities:

• running (n=6),

gardening

- gymnastics (n=5),
- strength training (n=5),
- cycling (n=4),
- walking (n=4),
- tennis (n=2),
- table tennis (n=2),
- ballroom dancing (n=2),
- nordic walking (n=2),
- horse riding (n=1).

2.3.2 Patients with cardiovascular disease

The group labelled "cardiovascular patients group" was composed of 3 women and 7 men. Their anthropometric data are shown in Table 2. They mainly showed ischemic cardiovascular disease (coronary artery disease with myocardial infarction treated by angioplasty, peripheral artery disease...) (n=7), hypertension (n=2) and one female patient showed a stress cardiomyopathy (Tako-Tsubo). In 5 patients (including all females), the body mass index was considered as in the normal limits according to the World Health Organization (WHO)⁵. Four male patients were overweight (body mass index over 25 kg.m⁻²) and one male patient exceeded 30 kg.m⁻². This last overweighed 72 yrs old patient with coronary artery disease, carotid stenosis, hypertension, showed a lot of cardiac risk factors, including tobacco.

Age (yrs)	Weight (kg)	Height (cm)		Body Mass Index (kg.m-
68.7 ± 6.5	67.7 ± 18.3	165.2 ± 9.5		24.4 ± 4.3
(60-77)	(48-106)	(150-177)		(19.5-34.2)

Table 2: Main anthropometric data in cardiovascular patients group. Data are expressed by mean ± SD (min-max).

These subjects were mainly practising weekly the following physical activities:

- walking (n=8),
- gymnastics (n=5),
- cycling (n=3),
- **strength training** (n=3),
- ballroom dancing (n=3),
- tennis (n=1),

- gardening (n=2)
- tinkering (n=1)

⁴ WHO classification Web page : <u>http://apps.who.int/bmi/index.jsp?introPage=intro_3.html</u>

⁵ WHO classification Web page : <u>http://apps.who.int/bmi/index.jsp?introPage=intro_3.html</u> D6.5 PAMAP Clinical Trials

- table tennis (n=1),
- nordic walking (n=1),
- volley-ball (n=1).

2.3.3 Patients with functional limitation

The functionally limited patients group was composed of 6 women and 4 men. Their anthropometric data are shown in Table 3. They mainly showed osteoarthritis (all female patients) in shoulder (n=3), spine (n=1), and gonarthrosis (n=1). Four male patients had a stroke, and the last patient (female one) had knee prosthesis after severe osteoarthritis. In 5 patients (including all females), the body mass index was considered as in the normal limits according to the World Health Organization (WHO)⁶. Three male and 2 female patients showed an overweight (body mass index over 25 kg.m⁻²) and one male patient exceeded 30 kg.m⁻².

Age (yrs)	Weight (kg)	Height (cm)	2)	Body Mass Index (kg.m-
71.6 ± 8.3	67.6 ± 11.5	161.9 ± 7.8		25.6 ± 2.5
(60-85)	(48-88)	(150-171)		(21.1-30.1)

Table 3: Main anthropometric data in functionally disabled patients group. Data are expressed by mean \pm SD (min-max).

These subjects were mainly practising weekly the following physical activities:

- walking (n=10),
- gymnastics (n=6),
- cycling (n=1),
- **strength training** (n=1),
- running (n=1)
- ballroom dancing (n=1),
- water aerobics (n=1)
- tinkering (n=1).

Some of these activities (bold font) were sometimes performed in fitness centers including strength training using machines.

⁶ WHO classification Web page: <u>http://apps.who.int/bmi/index.jsp?introPage=intro_3.html</u> D6.5 PAMAP Clinical Trials

3 PAMAP CLINICAL TRIALS DESCRIPTION

As described in Deliverables D2.4 (Revised User Requirements) and D2.5 (Revised System Specification), then in D3.4 and 4.4, the PAMAP system follows a holistic approach for physical activity monitoring by supporting both types, **aerobic activities** that are performed to prevent cardiovascular, metabolic and osteoporosis risk factors, and **strength exercises** that promote muscular strength and partly prevent the risks of falls and arthritis complications. Both of them are needed, since they cover different but complementary aspects of the physical health.

Now, the practice of these two different physical activity types also implies specific aspects for their monitoring and support. Monitoring daily living and aerobic activities (such as walking, running or cycling) that are performed over a relatively long period of time and at a specific intensity implies to determine global parameters, such as frequency, intensity, type, and time (FITT principle) based on a reduced sensor setup. Strength training implies the repetition of short and specific exercises and requires an accurate realisation and body positioning. Monitoring these strength training exercises implies then to help the individual to perform the exercises correctly, which requires accurate tracking of the body segments with an extended sensor setup, evaluation of more specific movement parameters (such as number of repetitions and sets performed, movement speed, amplitude, and smoothness) and an elaborated tutorial mode and online feedback mechanism. Both activity monitoring scenarios are supported by the final PAMAP prototypes and have been tested in two different phases of the clinical trials that are described next (*cf.* Deliverables D3.4, D4.4, and D5.4 for a longer description of the architecture and system components).

The clinical trials have been conducted in two independent phases: at hospital with PAMAP system used as a personal coach supervising a strength training session, and movements monitoring, and at subject's home during real daily life with daily and aerobic activities monitoring and web-based Electronic Health Record consulting:

- Hospital phase: This part of the clinical trials aimed to record accurately specific strength exercise movements in order to test the validity of the PAMAP prototype to track and monitor the movements in real-time and to visualize them on the TV screen and provide feed-back related to false movements. The guidance during an automatic and virtual trainer exercise session and the overall user interface was also tested.
- Home phase: This part of the clinical trials aimed to monitor daily and aerobic activities among real life conditions, to get a complete overview of activity type and intensity profile, and also to test the online user interface provided as a graphical summary of the monitoring results (as described in D4.4) and the use of the Electronic Health Record as described in D5.4. This Electronic Health Record (EHR) and Care Management application with web and i-TV interfaces enables management, sharing and reviewing of collected activity data, and facilitates healthcare professionals in the maintenance of a comprehensive medical record of their patients, and in the establishment and follow up of personalized rehabilitation and physical activity plans for them (as it is described in D5.4).

3.1 At hospital

3.1.1 Time-line

The clinical trials related to this phase took place from the 13/02/2012 to the 23/02/2012 at Pontchaillou hospital, Sports Medicine service, in the workroom of the sports trainers. This

room has been excluded from hospital visits for the trial duration. Its arrangement and Internet connectivity were dedicated specifically to PAMAP project with the help of the hospital IT department. This room was chosen partly because of the weak magnetic field perturbations inside, as previously measured by DFKI. It beneficiates from a national agreement related to investigations on healthy subjects that has been joined to the Ethics Committee file.

Ten days were planned to record the data related to the 30 subjects. On the first day of the experiment, only one subject was programmed on the morning, and two other ones in the afternoon, in order for the different partners who participated to the trials to be familiarized with a collective work in a medical area, and also to prevent possible technical problems and resolve them without cancelling or reschedule any appointment. The schedule of the subjects' appointments has been totally completed 15 days before. All subjects were phone called in the evening before their next visit, in order to plan a possible replacement in case of illness etc., and also avoid any neither mistake nor omission.

For each subject, the complete experiment (from the arrival to the departure from the facility) lasted less than 2 hours. A short and technical summary of the protocol is joined in the Appendix 5 of this report.

3.1.2 Experimental set-up

The prototype used at hospital was dedicated to monitor but also to conduct a session of muscular strength training. On a patient's point of view, PAMAP system simply appears as a TV linked to a computer (Figure 1), and a set of sensors.



Figure 1: PAMAP prototype used for strength session.

Ten IMU sensors were fixed on the subject (based on a specific body suit using velcros, Figure 2). Five sizes of suits allowed choosing the best size for each individual, both for males and females.



Figure 2: Sensors based on a specific body suit using velcros.

All along the session guided by PAMAP prototype, the Vicon device was recording the movement in order to have a reference system for the body tracking. Infra-red cameras were disposed all around the patient (Figure 3).



Figure 3: Three of the 8 Vicon cameras around the subject.

All data sent by PAMAP sensors were recorded in a computer and could be readable immediately by the research engineer (Figure 4).



Figure 4: Screen illustrating the movement data sent by PAMAP sensors.

Each session consisted in 8 various strength exercises (4 for upper body and 4 for lower body). Among these 8 exercises, 3 were chosen in order to be able to be performed by all subjects, whereas 5 were specific to each group (healthy subjects, cardiovascular disease group or functionally disabled group). All these exercises had been previously entered in PAMAP prototype separately according to the 3 groups of subjects (thus, the session was partly different in regards to the group of the subjects) (Figure 5). Moreover, each exercise beneficiated from 2 pictures and one video related to its realization (*Cf.* Appendixes 3 and 4).



Figure 5: Welcome on the virtual trainer (TV screen): the subject can choose the session of exercise related to his(her) group, using remote control.

3.1.3 Protocol

Exercises teaching

All exercises were firstly performed under human coach supervision in order to record the "gold standard" movements of each individual (Figure 6). The sensors sent data to PAMAP prototype in order for it to further give a feed-back to the subject, related to the quality of each movement. After this phase, sensors dedicated to Vicon system were added on the subject.

Then the TV was switched on.



Figure 6: "Gold standard" recording under human supervision before PAMAP prototype use.

Familiarization procedure

After explanations from the human coach, related to TV and remote control functioning, the subject interacted freely with the system. During this phase, the subject interacted with the system through the remote control in order to discover the different functionalities offered by the system.

During this phase, in particular, the subject could look at a tutorial related to PAMAP functioning (with slides and sound, on the TV) (Figure 7). This tutorial explained the need to calibrate the system, and how to do it, and also how to choose the session to perform, and how to go from one to another exercise. It explained also that the system could give feed-back and alert the subject when a movement was poorly performed. Moreover, it provided educational material concerning the conduction of strength exercises.



Figure 7: Patient looking at the PAMAP tutorial on TV screen.

After reading and lessoning the tutorial (few minutes), the subject went on the icon dedicated to the calibration of the system.

Measurement protocol

From this moment, the IMUs placed on the subject were used to offer a real-time interaction between the subject and the PAMAP system. The subject could in particular visualize his (her) avatar on TV screen.

The subject alone then performed the calibration of the system, guided by the PAMAP system through the TV interface (Figure 8). In particular, the subject received instructions related to the postures to maintain (Figure 9).



Figure 8: Calibration of PAMAP prototype: the patient follows TV instructions



Figure 9: Puppet during calibration of PAMAP system.

After calibrating the system, the subject went on the icon specific to his (her) group in order to perform the training session that consisted in 8 various exercises. The subject followed the instructions of PAMAP prototype via TV screen only (human coach did not interrupt the automatic session) (Figure 10). The human coach only talked to the subject if he (she) did not breath correctly during the exercise, as the current PAMAP prototype could not detect the subject breath.



Figure 10: Patient performing her session, only using TV instructions and feed-back.

This phase was divided into 2 sub-phases:

- semi-automatic mode: 10 exercises (including right and left body side, thus 5 various movements in fact) performed without any oral feed-back of the machine (no counts, no feed-back related to the quality of the movement). The patient must go on the next exercise when one was finished, using the remote control.
- full automatic mode: 6 exercises (including right and left body side) fully guided by the machine (with counts of the repetitions and guidance related to the quality of the movement in case of false one). The patient did not have to use the remote control anymore (only if he wanted to look at a video for example).

The semi-automatic phase was used to evaluate the ease of the subject to interact with the PAMAP system and to go through his (her) exercise program.

The automatic phase was used to test the program developed for movement evaluation.

During the full automatic phase, when a patient has performed a wrong movement, he (she) was helped by the prototype in order to perform closer to the "gold reference" movement: a message was clearly edicted by the TV with a visual demonstration (Figure 11). At any moment, the patient could have a look to the video of the movement by pointing on the pictures that are always at the left of the screen.



Figure 11: Message from the PAMAP prototype related to a wrong movement.



When a set of repetitions ended, the subject was encouraged by the prototype (Figure 12).

Figure 12: Message from PAMAP prototype related to encouragement.

At the end of the exercise program, an abstract of the quality of the session appeared on TV screen, giving a global feedback to the patient related to the strength exercise session (Figure 13).

At the end of the session, each subject completed the surveys related to PAMAP use and socio-cognitive questionnaires. He (she) was invited to describe what he (she) has thought about this guided exercise session, with the advantages and limits of PAMAP use.



Figure 13: Resumed feed-back related to the quality of the movements performed during the semiautomatic mode.

3.1.4 Measured and collected data

Various data were recorded and collected during this hospital session, for each subject:

- Collected IMU data and Vicon reference for evaluating IMUs and inertial body tracking methods developed in WP4, Individual "gold standard" movements for each of the selected strength exercises (manually labelled) performed under supervision of the physical activity trainer, and the same movements performed by the subject without any human help for evaluating the motion monitoring algorithms developed in WP4,
- Videos documenting the interaction of the subjects with the system and their motions for evaluating both the user interface and the exercise monitoring algorithms (based on the videos, the correctness of the performed motions from physical activity trainer's point of view can be judged providing human ground truth),
- Answered questionnaire on the User Interface developed in WP5 for evaluating the usability of the system (*cf.* Appendix 6),
- Answered socio-cognitive questionnaires for evaluating motivating factors (intrinsic, extrinsic...), beliefs, attitudes and behaviours towards physical activity practice (*cf.* Appendix 7)
- Subjective notes taken by a research engineer concerning the interaction of the first subjects with the PAMAP system (based on observation).

3.2 At home

3.2.1 Time-line

The clinical trials related to this phase took place from November 2011 to June 2012. Ten months were then used to measure each of the thirty subjects.

For each subject, the complete experiment (from the installation of the device to its removal) lasted one week (*cf.* short and technical summary of the protocol in Appendix 8).

3.2.2 Experimental set-up

This part of the clinical trials aimed to monitor daily and aerobic activities among real life conditions, to get a complete overview of activity type and intensity profile as described in D4.4, and also to test the online user interface (also described in D4.4) and the use of the Electronic Health Record (as described in D5.4).

Each hardware set-up was composed of:

- 3 IMU sensors with specific fixations,
- 1 dongle for the IMUs,
- 3 chargers, 1-1 for each of the IMUs,
- 1 heart rate monitor,
- 1 dongle for the HR-monitor,
- 1 Texas Instruments watch,
- 1 mobile unit (micro-computer) with a specific pocket holster, to wear at the belt or at the shoulder,
- 1 set-top-box and its grey remote control,
- 1 laptop,
- 1 TV and its black remote control,
- 1 HDMI cable to connect the set-top-box to the TV,
- 1 Ethernet cable to connect the set-top-box to the laptop,
- 1 user manual translated in French related to PAMAP device and internet connectivity,
- 1 activity notebook (paper format)
- 2 electrical power strip extensions to connect sensors, mobile unit, laptop, set-topbox and TV.

The sets-up used for the home clinical trials are more accurately described in Appendix 9.

The CIC-IT engineer brought the TV screen when necessary only (n=7, in whom TV was too old to support HDMI connectivity). Twelve subjects already had a TV with HDMI connectivity and 11 subjects, among the oldest, did not want to use Internet and EHR. Thus the 19 subjects (quite 2/3 of the studied sample of ageing people) who accepted to try to connect to Internet and EHR have used a laptop. Subjects who did not want the TV and/or set-top-box and laptop had never used Internet and did not want to use it, even with the explanations of the engineer and under his help.

TV remote control must be used only to switch the TV on then off, whereas the set-top-box remote control was used to explore the EHR and go from one to another menu. Indicative screenshots of the TV interface of the EHR are presented in Figure 14.

				WarmUpphase
Mesures	Mesures	Nom de l'Exercice	Durée	Intensité
🥪 Vidéos	Vidéos	walking running		normai moderate
Questionnaires	Questionnaires	cycling		moderate
O Visites Médicales	Visites Médicales			
Yrise en Charge	Prise en Charge			
📾 back 🗢 alde 🙆 👽 haut/bas 🛛 🐼 CK 🕜 acc	ueil 🚗 back 🗢 aide 🙆 🧒 haut/bas	📾 OK 🛛 🍙 accueil 🛛 🛁 back 🔍 e aide	🛆 🗑 haut/bas 🛛 🎯	🖻 gauche/droit 🛛 🔿 CK 🛛 👩 accueil

Figure 14: Indicative screenshots of the TV interface of the PAMAP EHR.

Subjects who accepted to use Internet and EHR had to switch on the computer, put the 3G-key in the USB connection, connect to their Internet server, and then connect to the EHR server located in the CIC-IT. This manipulation has been shown 2 or 3 times by the CIC-IT engineer when he set up the device at subject's home. Some subjects phoned him to ask again how to do

this manipulation (one call, on the first 3 subjects). Thus, the user manual has been revised in regards to this point in order to better explain how to connect. After that, no voluntary subjects had particular difficulties to connect to Internet and EHR.

3.2.3 Experimental procedure

Before the set-up at subject's home, the CIC-IT engineer entered main anthropometric and heart rate (resting and maximal predicted) data on the web based user interface of the PAMAP EHR (weight, height, birthdate, and sex, **Fehler! Verweisquelle konnte nicht gefunden werden.**). After that, he attributed a mobile unit number in the subject's EHR and downloaded these data on this mobile unit. When the Wi-Fi connectivity between the mobile unit and the EHR did not function (lack of internet connection), these data were manually entered on the mobile unit.

pam AP Electron	ic Health Record	RACOM			Rechercher un Patient	Nouveau Patient	Mon Profil	R Déconnexion
A Détails personnels	Aperçu CProfil de Santé	Visites Médical	es 🧷 Tests Médicaux	Gestion des diagnostics	Gestion des traitements	/Prise en Charge	Résumé	
Détails personnels								
Prenom*: n*5	Nom	*: s	ujet				Info	rmation de nexion
Nº Sécurité Sociale*: 2420 Nom du Père*:	ar Date	de Naissance*:	24-07-1942				Iden Jean 1	ifiant: Marc Foricher
Adresse:			dd 1411 9999				Pati	ent
Téléphone Mobile#: Email:	Accu	eil#:	e fichier) aucun ficectionné					
Détails des Relatifs Prenom:	Nom							
Numéro de Téléphone #1:	Num #2: Confirmer	éro de Téléphone.					Prén sujet 1 N° Sé 24207	om: 1°5 curité Sociale. 735

Figure 15: Print screen from the web based user interface of the PAMAP EHR menu illustrating anthropometric data menu.

Moreover, each subject has previously informed the CIC-IT engineer about his (her) daily physical activity program, one to five days before beginning this home phase. On the basis of this, each individual's physical activity daily planning was recorded in the web EHR and permanently stored on the PAMAP server located at the CIC-IT (Figure 16).

alls personnels	tronic Health Record					S Rechercher 1 Patient	an Mouveau Patient	Profil	(ð) Déconnexi
the state of the second st	Aperçu Profil de San	nté 🔶 Visites	Médicales T	ests Médicaux	Gestion des dia	Gestion des traitements /Prise en Charge Résumé			
onner Configu	uration Rapports Ordre du	ı Jour							
Mesures V	idéo à Questionnaires	Visites	Programme					Int co	formation de onnexion
la dem	nande Vie	edicales	de Réhabilitation					Ide: Jean	n tifiant: n Marc Foricher lo
Plans d'Enti	rainement							Pa	atient
Programme De Nom* Date de Début ³ Date de Fin*	*								
tecommandat Pousionésurés Fréquence caro Préquence caro Préquence caro casoquinanées	diaque diaque dites* diaque							Pré suje N*1 242	énom et n°5 Sécurité Sociale 10735
Sensation de D	Dyspnée	=						Pr	rise en Charge
Percue	Douleur							Nor	m: n pamap
Sensation de D Reccue									
Sensation de D RSEE¥ ^e Ajouter ce nouve	eau P		1						
Séntation de D RSESS ^e Ajouter de nouve	eau Pj		Ŀ						
Sénéation de D R8654ª Ajouter ce nouve Supprimer la séle	eau P eci								
Sénéation de D Réteve Ajouter ce nouve Supprimer la séle Plan List	eeu P eeg 🛛 🖌 🗆								
Ajouter ce nouve Supprimer la sélé Plan List 1940	esu P	Notes 1	Date de Début	s. Date de Fin	* Action				
Ajouter ce nouve Supprimer la sélé Plan List U=10	ee P Nom , muscu en sale sujet 5	Notes 14	Date de Début 13-12-2011	bate de Fin 13-12-2011	** Action				
Ajouter ce nouve Supprimer la sélé Plan List Sélectionner	eau P	Notes 16	Date de Début 13-12-2011 14-12-2011	 Date de Fin 13-12-2011 14-12-2011 	*• Action Voir				
Ajouter ce nouve Supprimer la sélé Plan Liat I+%) Sélectionner	eed V .	Notes a	Date de Début 13-12-2011 14-12-2011 15-12-2011	 Date de Fin 13-12-2011 14-12-2011 15-12-2011 	*• Action Voir				
Ajouter ce nouve Supprimer la sélé Plan List Sélectionner	ecc	Notes a	Date de Début 13-12-2011 14-12-2011 15-12-2011 15-12-2011	 Date de Fin 13-12-2011 14-12-2011 15-12-2011 16-12-2011 	* Action Voir Voir				
Ajouter ce nouve Supprimer la séli Plan List 3+00 2-00 2-00 2-00 2-00 2-00 2-00 2-00 2	eere Nom Nom Nom Nom Nom Nom Nom	Notes .	Date de Début 13-12-2011 14-12-2011 15-12-2011 16-12-2011 16-12-2011	 Date de Fin 13-12-2011 14-12-2011 15-12-2011 16-12-2011 17-12-2011 	* Action Voir Voir Voir				
Ajouter ce nouve Supprimer la séli Plan List Sélectioner	eed Mom Muscu en sale sujet 5 denenagement et marche gym gof muscu muscu et ettysge muscu tigkre ovri	Notes (4)	Date de Début 13-12-2011 14-12-2011 15-12-2011 16-12-2011 17-12-2011 18-12-2011	 Date de Fin 13-12-2011 14-12-2011 15-12-2011 16-12-2011 17-12-2011 14-12-2011 	rs Action Voir Voir Voir Voir				

Figure 16: Example of a physical activity weekly planning, daily defined, in one subject.

After the engineer brought the device to the subject's home and demonstrated how it was functioning and what the subject had to do daily, the 30 subjects should daily use their EHR on the TV in order to check their physical activities daily planning (Figure 16).

They also had to test the functionalities of their EHR by completing some surveys, previously chosen and programmed on the EHR by the CIC-IT engineer (Daily Health Profile, Dartmouth Quality of Life Index, and Quality of Life QLMI2, cf. Appendix 10), in the aim to test the EHR use (Figure 17).

0 0 0 https://93.93.15_31	Quality of LifeQLMI-2 ubdet1rub2 × 🖉 Quality of LifeQLMI-2 × 🔯 http://93.93.1		Amer//819135 Handerland × Champ/(81911	Mozilla Firefox		
 93.93.153.205 Most Visited * 	8082/index.php V C 🖓 - 1 BHR.& PHR.Vs + 🎦 H.NAYTEMDOP + 🛄 FP71/CT & Ags + 🔛 HL2 material + 🔄 BHR.Overview H 🔛 BLP - 💭 Propes	blue star Q, 🌸 al Meas * 🔅 🖬 Bookmarks *		2695questid=767386lang=en ☆ ♥ ♥ ♥ ♥ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	Q 💽	
	Quality of Life-QLMI-2	ſ	Qu	estion	Answer	n
	We would like to ask you some questions about how you have been feeling during the last two weeks		In general, how much of the time during the last two weeks have you felt fro	ustrated, impatient or angry?	None of the time	
	0% 100%		How often during the last two weeks have you felt worthless or inadequate?	1	A little of the time	
	pagel		In the past two weeks, how much of the time did you feel very confident an	d sure that you can deal with your heart problem?	All of the time	
	•In general, now much of the time during the last two weeks have you felt trustrated, impatient or angry?		In general how much of time did you feel discouraged or down in the dump	s during the last two weeks?	None of the time	
	Choose one of the following answers		In the past two weeks, how much of the time did you feel relaxed and free of	of tension?	All of the time	
	O All of the time		how often during the last two weeks have you felt worn out or low in energy	y?	A little of the time	
	O Most of the time		How happy, satisfied, or pleased have you been with your personal life duri	ng the past two weeks?	Happy most of the time	
	G A good bit of the time Some of the time		In general how often during the last two weeks ha ve you felt restless, or as	if you were having difficulty trying to calm down?	None of the time	
	O A little of the time		How much shortness of breath have you experienced during the last two we	eeks while doing the day to day physical activities?	Moderate shortness of breath	
	O Hardly any of the time		How often during the last two weeks, have you felt tearful, or like crying?		None of the time	
	U None of the time		How often during the last two weeks, have you felt as though you were more	re dependent that you were before your heart problem?	None of the time	
	How often during the last two weeks have you felt worthless or inadequate?		How often during the last two weeks, have you felt unable to do your usual	social activities, or social activities with your family?	None of the time	
	Choose one of the following answers		How often during the last two weeks have you felt as if others no longer has	we the same confidence in you as they did before you had the heart moblem?	None of the time	U
	O All of the time		How often during the past two weeks have you experienced chest pain while	e doine your day to day activities?	None of the time	L
	O Most of the time		How often during the but two works, have you felt uncere of yourself or but	ching in self-confidence?	Hurdly any of the time	L
	Some of the time		How often during the last two weeks have you ten unsure of yourself of the	nul less?	Hurdly any of the time	н
	O A little of the time		During the last two works how much how you been limited in doing mosts	or exercise as a result of your heart problem?	Not limited at all	L
	O Hardly any of the time		How often during the last two works have you felt annehension or frichten	or energies to a result of your many profilem:	None of the time	T
	O None of the time		How often during the last two weeks have you felt divys or lightheaded?		None of the time	ļ
	•In the past two weeks, how much of the time did you feel very confident and sure that you can		inter once oning me met not receas nave you ten unzzy or rightmenden.		rome or ane sudie	×,

Figure 17: Example of a survey directly completed on the EHR and the associated report presented to the clinician.

Each subject had to wear 4 sensors on his body (HR monitor included), with a central IMU one located just above the heart rate monitor on the torso (Figure 18). The watch of the heart rate monitor was worn on the left wrist.



Figure 18: Upper body and torso sensors. Each subject was wearing 4 sensors during this phase of the trials: 3 IMUs and a HR-D6.5 PAMAP Clinical Trials

monitor. These sensors are placed onto 3 different body positions. A chest sensor fixation includes one IMU and the heart rate chest strap (Figure 18). The second IMU is attached over the wrist on the right arm, and the third IMU on the right ankle, both are fixed with sensor straps (Figure 19). The patient's current heart rate is shown by the TI watch, worn on the left wrist (Figure 18). All subjects were able to wear the sensors without the help of another person.



Figure 19: Upper and lower limbs sensors.

Then he (she) switched on the mobile unit (micro-computer with touch screen) before performing his (her) daily physical activities (Figure 20). He (she) could wear this prototype for the active part of the day before charging sensors and mobile unit. Every subject could perform his (her) usual activities without being significantly affected by the setup.



Figure 20: Mobile unit used with the touch screen.

After having switched on the mobile unit, the subject starts the activity monitoring software by clicking its icon. The window of the software opens with few icons showing various activities (Fehler! Verweisquelle konnte nicht gefunden werden.).



Figure 21: Icons appearing after having entered in the activity monitoring software, on the mobile unit.

At any time, the subject can access an online user interface providing a graphical overview of the physical activity profile of the current day (Figure 22).



Figure 22: Summary of the recognized activities performed by a PAMAP subject. The icons in the top left corner (A, C and H) are indicating that the 3 IMUs are working properly (green colour). The patient's current heart rate is shown below these icons, 81 beat/min⁻¹ in the example.

Then the subject put the mobile unit in a specific bag at his (her) belt or at shoulder strap, or near them (depends on their activity) (Figure 23).



Figure 23: Mobile unit in its pocket, worn at the belt

Furthermore, all along the day, each subject had to label their physical activities in order to obtain ground truth and training data for the activity monitoring algorithm. This could be done either through a specifically developed user interface on the mobile unit by activating an icon (Figure 24), or by noting down the physical activities on a blank paper notebook. Partly due to robustness issues with the mobile unit as described later in Section 4.1.2 and due to the subjects being more familiar with writing on a paper, the paper notebook was the preferred medium. After completion of the protocol, the notebook content was recorded on a file at the CIC-IT, translated in English and shared with DFKI (*cf.* Appendix 11).



Figure 24: Instead of completing a paper physical activity notebook, the subject can label his (her) activities using the mobile unit, after being entered in one of the main menus (Sport activities etc.).

At the end of each day, the subject left the activity monitoring software, switched off the mobile unit, and charged the sensors and the mobile unit.

At the end of the week, the CIC-IT engineer came to the subject's home to collect the device and the daily activity notebook. He checked the activity notebook and asked for further explanations if needed and if the subject could remember his (her) activities. He also noted the comments of each subject on his (her) case report form.

At the inclusion visit (just at the beginning of the protocol), the subject had to complete some of the socio-cognitive questionnaires in order to assess his (her) motivation. Some of these surveys were also completed at the end of this week, if the subject had totally completed the full protocol (hospital and home phases). Then, when Internet connectivity was functioning, the CIC-IT engineer uploaded the collected data on the EHR of the subject. He also copied the data stored on the mobile unit on a USB key and uploaded it to the secure PAMAP WebDAV using Cyberduck software in order to make it available to all partners.

When the subject finished the protocol (hospital and home phases), the CIC-IT engineer updated his (her) case report form in order for the CIC-IT to be able to answer to a possible quality control (*cf.* Appendix 12). In this way, a quality engineer must have checked all forms. Such forms will be kept at the CIC-IT for 20 years.

3.2.4 Measured and collected data

For each subject, the following data were collected:

- Measured IMU data, heart rate (recorded along with IMU data) and manually written physical activity notebooks (after translation in English and upload on the WebDAV) as ground truth for performed activities to evaluate the activity recognition algorithms developed in WP4 and to obtain labelled training data.
- Socio-cognitive questionnaire answers (for evaluating motivating factors, limitations towards physical activity etc.). They were scanned and the PDF files were uploaded to the WebDAV in order to make the data available to all partners.
- Data uploaded to the EHR (Fehler! Verweisquelle konnte nicht gefunden werden.), with pdf report (Figure 26).

000							Mo	zilla Firefox						
https://93.93	.1olumn4	:MPALink	[+]											
93.93.1	53.205 htt	tps:// 93.	93.153.205:8	181/pamap/	faces/Test	Results.jsp?	form1:layoutP	anel31:tabSet	1:tab1:la	ayoutPanel1:rest	ltsT. ☆ マ C	🚼 - blue star	٩ 1	
Most Visited	🕶 🚞 EHR	t & PHR V	e 🔻 🔝 H	ΝΑΥΤΕΜΠΟΡ	🔹 🚞 I	FP7: ICT & Ag	ge 🔻 🚞 HI	L7 material 🔻	() EH	R Overview H	🚞 RUP 🔻 📋	Proposal Ideas 🔻	» 🛃 Bookmark	•
														n
nam A	P.									Find Patient	New Patie	nt 🛛 🚰 My Profi	ile 🚷 Logout	
рашл	L Elect	ronic Hea	alth Record		LICOM				\bigcirc		T			
2 Personal D	etails 📙	Overvi	ew 💭Hea	lth Profile	🕴 Visits	Tests	CDiagno	sis 🍾 Trea	tment	Care Plan	Summary			
Test Orders	Pending F	Results	Test Resul	t Details T	est Result	ts Graphs								
														U
													Login Information	L
Observ	ation Requ	uest											Login User Name:	1
													Jean Marc Fortcher	1
Test Family			Activity Mo	nitoring Test	-								Patient	1
Observ	ation Requ	uest	2012-01-2	8 10:31:09	•									L
Submit														1
TEST	VALUE*	UNITS	DATE	DESCRIPTI	ON	OBSERVER	Ac	tion						1
Activity			2012-01-28				A	ttachements						1
Monitoring Test			10:31:09											1
													Patient Name	L
													Social Security No.	1
													2460135	1
														L
														1
														1
														Ŧ
														- //,

Figure 25: PAMAP measurements overview.



Figure 26: Example of a pdf report related to PAMAP measurements.

4 CONCLUSION

This section concludes the trials report. It provides qualitative comments, suggestions and feedback collected during the trials and gives a perspective on further data treatment.

In general it is worth noting that during neither clinical trials, no drop out nor adverse event was noted. All subjects were pleased to participate to this study, even if some of the oldest were reluctant to Internet use and could not test EHR at home.

4.1 Global subjects feelings

All subjects recognised the need to regularly perform physical activity (good for health) but also their difficulty to be always motivated and compliant with their program, also during winter and if the weather is bad. Thus, after using PAMAP prototype, all subjects were pleased that science is working to help them in maintaining physical practice using current technologies.

All enjoyed to participate in this highly technologic research. They were very compliant in regards to our protocol, however quite differently between hospital and home recordings.

Questionnaires were used to evaluate the feeling of the subjects regarding the PAMAP system. **Fehler! Verweisquelle konnte nicht gefunden werden.** shows an example of the free comments that the subjects could provide regarding the system for strength exercise monitoring.

Subject	Category	Answer
1	Н	To be able to modify the number of repetitions
2	Н	Nothing to report
3	С	Clear and well precise
4	Н	-
5	Н	-
6	F	-
7	С	The questions from this questionnaire are inappropriate. Grey background grey writing; to
8	Н	Regarding the mobile unit (not easy to plug?)
9	С	-
10	Н	Simplification of the sensors for a frequent domestic use
11	Н	-
12	Н	-
13	С	That the TV picture be in the good direction
14	С	-
15	Н	Different levelS of GUI (familiarisation, current use)
16	F	•
17	F	-
18	С	No modification
19	С	·
20	F	To increase the sound
21	С	·
22	F	No, it's very good
23	F	-
24	F	Lecture of the help too fast
25	Н	-
26	F	-
27	F	None, it seems already to be well designed
28	С	-
29	С	-
30	F	Nothing to declare

Table 4: Free comments/suggestions given by the subjects in the questionnaire regarding the PAMAP system evaluation (direct translation from the French answers). Categories: H Healthy subject, C and F, cardiac and functional patient, respectively.

4.1.1 At hospital

Many patients showed some apprehension before the experimental procedure, fearing that they couldn't manage to manipulate a new technology. At the end, all the subjects recognized how easy it was to interact with the system and to understand the instructions.

Positive comments

All subjects were very interested in seeing their avatar on the TV screen. That was a nice way for them to correct their posture in real time and accurately in order to avoid bad posture and risk to hurt them. All enjoyed a lot this technology and had also a big pleasure to have an exercise session completely programmed on the TV, with pictures and videos of each exercise.

Subjects fully appreciated the complete automatic mode, counting the number of repetitions and going from one exercise to the next one automatically.

All subjects were pleasantly surprised by the encouragements given by the device. They also appreciated the feedbacks when their movements were wrong compared to the "gold standard" one.

After a short demonstration and looking at the tutorial (whereas the slides were a little too fast), all subjects were able to use alone the PAMAP device (*cf.* Appendix 13). They found it useful to train at home following the prescription of a professional sport coach or physician. They also appreciated the possibility for these professionals to check their sessions and the quality of their movements.

Suggestions for improvements

For greater personalization, each subject may choose his own avatar among few models, as maybe the orientation of the movements performed on the TV screen (the avatar could move strictly as the subject does, or in mirror).

Furthermore, pictures may be a little bigger as some subjects had to approach the screen to look at them accurately. Some videos were diffused on a landscape horizontal mode instead of portrait vertical one such as the subjects had to turn their head to look at them. These pictures and videos should also show the movement in front and lateral modes.

Videos could also explain when the subject has to breathe during the movement, because during strength exercise, a non-expert tends to retain his (her) breath or does not breathe in agreement with the movement.

Different levels of instructions could also be proposed. This will enable to provide an interface adapted to the familiarization of the subject with the PAMAP system and physical activity practice: for example, beginner, advanced, expert.

The subject can always see a picture showing a dumbbell in the left upper corner of the TV screen, with a number showing the weight that should be lifted by the subject (0 kg if no dumbbell). This picture should be removed in case of no dumbbell use for a better understanding. At the contrary, when a dumbbell or a Swiss ball (for example) must be used, that should be emphasised in some instructions before beginning the exercise.

In order to improve automatic mode instructions, these instructions could be orally specified when a new set of repetitions begins again.

Moreover, when a movement is falsely performed, the repetition should however be counted in order to not overtrain the subject (with an error message giving feed-back and instructions for a better performance).

The summary given at the end of the session is too shortly showed, the subject could not read it accurately. That should stay on the TV screen for a longer duration.

4.1.2 At home

Twenty-nine subjects have tested the home device for one week. Technology acceptance was an issue for just one subject (stress related to computer use). This healthy subject has tested the device for 2 days only.

Positive comments

Related to the use of the i-TV interface of the EHR

All set-top boxes were well functioning all along the clinical trial. Moreover they were easy to switch on and off.

Subjects greatly appreciated that the EHR never bugged. Navigation in the EHR was simple using the specific remote control of the set-top-box. Inside the EHR, two colours indicated if some sub-menus were present or not. For example, a purple menu indicated that the subject should enter and look for sub-menus. At the contrary, a grey menu indicated that no sub-menu existed. These colours codes have been immediately understood from the first demonstration that the CIC-IT engineer has made.

Looking at their EHR, after having completed the first questionnaire together with the engineer, no subject showed any technical difficulty to complete the two other ones.

Related to physical activity recording

The device was easy to set up and the subjects did not perceive any constraints to wear the sensors. They were very interested by the sensors, heart rate monitor and movements recording.

No subject showed any difficulty to wear and fix the sensors. All subjects totally forgot the sensors during their physical activities.

Suggestions for improvements

Related to the use of the i-TV interface of the EHR

All 19 subjects were familiar with the remote control. However, even taking into account the colour difference, 3 subjects have shown some difficulties to choose which remote control they have to use for which task. Subjects should beneficiate from a unique remote control.

When the subject was on his (her) EHR, it took quite long time to go from one page to another one, so that some subjects expressed a little impatience. This duration was really seen as a constraint by each subject.

In order to enter some answers in the surveys the subject must use the remote control in order that a keyboard appears on TV screen. This was totally unusual for the subjects and did not seem really convenient for them.

However, looking at their EHR on their TV screen was not the priority of the subjects because they weren't forced to follow a specific physical exercise program. Indeed, the subjects were free to choose their daily program. They recognized that such communication mode with health professionals should be useful, however, with the request that the navigation from one to

another EHR page should be accelerated.

Otherwise, in order to be usually practiced in France, all the EHR content needs to be revised for a better French translation.

Related to physical activity recording

Subjects asked for more discrete sensors: one woman for example, was embarrassed to wear a skirt to go dancing, with a sensor at her ankle.

In highly dynamic activities, the subjects had to let the mobile unit near them, in order to avoid losing the contact between the computer and the USB key connected to it. This point must and can be easily improved.

Furthermore, at home, two prototypes could be used simultaneously (instead of 3, for technical reasons: only 2 mobile units available). Thus home recording duration has been much longer than programmed, as also one of the mobile units was dysfunctioning on the last month (thus this part of the protocol ended with only one prototype).

Thus, more robust hardware and hardware that is better integrated in daily living is needed for the setup. This will be possible, thanks to nowadays powerful mobile processing units and miniature sensors.

It's interesting to note that the autonomy of the mobile unit was a limitation, contrary to sensors one (3 vs. 5 hours). The autonomy of the battery got worse during the months of the clinical trials, beginning at 5-6 hours and being after 6 months around 3h – 3h30. Moreover, the mobile unit became very hot, what was unpleasant for the subjects who wear it directly on their belt.

The size of the mobile unit should be decreased, however it did not seem too heavy for the subjects. On another way, the screen appeared of a too little size for ageing people. Some had problems to read the messages given by the mobile units. On this way, a mobile unit such as an IPhone with only verbal messages and a unique central icon may be better.

Sometimes the subjects were curious and opened the belt to look at the mobile unit.

Subjects could look at anytime at their activity summary on the mobile unit. This user interface was implemented to provide motivational elements to the subjects. Only 6 subjects used this functionality. The other subjects already well knew what they perform and such approach did not specially motivate them to continue to train. On another way, wearing a heart rate monitor motivated some subjects.

Data was also uploaded at the end of the protocol to the EHR and subjects should be able to see the summarized data also in the EHR (this was also implemented by ICOM and DFKI to provide some offline/long-term feedback to the subjects). Subjects were not particularly interested by this functionality, perhaps because that needed Internet connectivity.

Moreover, one cardiovascular subject was really inaccurate in his activities description; few subjects (n=8) should have more developed their activities description, so that the quality of notebooks varies a lot. Inaccurate activity notebooks result in a lack of labelled training data for evaluating the activity monitoring based on the pre-learnt models (cf. D4.4) and for supervised learning of new models. A daily phone call, strictly directed by the CIC-IT engineer may have partly resolved this lack of accuracy. However, such subjects could not remember very accurately what they performed during the day if they did not write it immediately. The original solution of providing a specific user interface for activity labelling was problematic due to the robustness issues mentioned above (the mobile unit needs to be removed from the pocket) and due to the subjects being more familiar with noting their activities on paper (which is usually done for physical activity recording).

4.2 Data treatment

As summarized in Sections 3.1.4 and 3.2.4, various data were collected during the trials in order to further evaluate the different aspects of the PAMAP system prototypes, i.e. the feasibility of the algorithms, but also the use of the system and the motivating factors of the subjects and their feelings related to the impact of PAMAP use on their motivation and compliance towards physical activity practice. All of this data has been made available to all partners on the PAMAP WebDAV and is under treatment at the partners' sites during the preparation of this report.

The first results related to socio-cognitive questionnaires concern the motives for physical activity. These motives have been assessed using the scale labelled "Motives for Physical Activity Measure – Revised " (MPAM-R).

This scale is a validated questionnaire intended to assess the strength of five motives for participating in physical activities such as weight lifting, aerobics, or various team sports⁷. The five motives are:

- **Fitness**, which refers to being physically active out of the desire to be physically healthy and to be strong and energetic;
- **Appearance**, which refers to being physically active in order to become more physically attractive, to have defined muscles, to look better, and to achieve or maintain a desired weight;
- **Competence/Challenge**, which refers to being physically active because of the desire just to improve at an activity, to meet a challenge, and to acquire new skills;
- **Social**, which refers to being physically active in order to be with friends and meet new people;
- **Enjoyment**, which refers to being physically active just because it is fun, makes you happy, and is interesting, stimulating, and enjoyable.

This scale has been previously used in various populations to predict various behavioural outcomes, such as attendance, persistence, or maintained participation in some sport or exercise activity, or to predict mental health and well-being. The different motives have been found to be associated with different outcomes.

This scale is a revision of an earlier measure by the same name, which was shorter and included only three motives (Frederick & Ryan, 1993⁸). The longer version was introduced and validated by Ryan, Frederick, Lepes, Rubio, and Sheldon (1997)⁹.

⁷ http://www.psych.rochester.edu/SDT/measures/mpam_description.php

⁸ Frederick, C. M., & Ryan, R. M. (1993). Differences in motivation for sport and exercise and their relationships with participation and mental health. Journal of Sport Behavior, 16, 125-145.

⁹ Ryan, R. M., Frederick, C. M., Lepes, D., Rubio, N., & Sheldon, K. M. (1997). Intrinsic motivation and exercise adherence. International Journal of Sport Psychology, 28, 335-354.

In our PAMAP studied population, the motives should differ from healthy to other groups, as the analysis of the prevalence of the 5 motives tends to support. However, given the restricted number of subjects in each group, this hypothesis needs to be verified and supported by a deep literature review. Please note that the coded answers to questions were converted to present the results evenly: When a motive is related to a score less than 4, that signifies that the subjects are not really concerned by this motive. When the score is equal to 4, this motive is not true however not false. If the score is higher than 4, this motive does surely play a role in the physical activity practice.

The short delay from the end of the clinical trials and the dead line of the clinical trials report only allow us to present some first and short descriptive results:

Fitness dimension (which refers to being physically active out of the desire to be physically healthy and to be strong and energetic) (Table 5). Remarkably, all subjects without exception are based on this ground for physical activity practice, even if some subjects feel more concerned than others in regards to this motive. This motive includes a health perception and is always used by the medical teams to encourage patients to engage in a regular physical practice. These results should also suggest that the relationship between a regular physical practice and health would be well perceived by everybody.

Scale	Whole group	Healthy subjects	CV group	Functional group
(0 to 7)	(n=30)	(n=10)	(n=10)	(n=10)
No (<4)	0	0	0	0
Middle (=4)	0	0	0	0
Yes (>4)	30 (100%)	10 (100%)	10 (100%)	10 (100%)

Table 5: Motive related to fitness. Prevalence and strength of this motive in the whole group and in separated groups. Results are expressed by the number of subjects and the related percentage.

Appearance (which refers to being physically active in order to become more physically attractive, to have defined muscles, to look better, and to achieve or maintain a desired weight) (Table 6). All healthy subjects are based on this motive to practice a physical activity. However, in cardiac and functionally limited patients, only half of them seem really concerned by this motive. However, due to the moderate intensity of the physical practice in patients, the appearance is not dramatically and quickly modified by the physical practice (not as much as in healthy population).

Scale	Whole group	Healthy subjects	CV group	Functional group
(0 to 7)	(n=30)	(n=10)	(n=10)	(n=10)
No (<4)	8 (26.66%)	0	4 (40%)	4 (40%)
Middle (=4)	2 (6.66%)	0	1 (10%)	1 (10%)
Yes (>4)	20 (66.66%)	10 (100%)	5 (50%)	5 (50%)

Table 6: Motive related to Appearance. Prevalence and strength of this motive in the whole group and in separated groups. Results are expressed by the number of subjects and the related percentage.

Competence/Challenge (which refers to being physically active because of the desire just to improve at an activity, to meet a challenge, and to acquire new skills) (Table 7). Quite similar results can be observed compared to the previous motive, even if 80% of the healthy population only seem concerned by this motive to engage in a physical practice. Currently, medical teams are not based on this motive to encourage patients to practice a regular physical activity, because of the risk of cardiac events of trauma linked to a possible self-transcendence.

Scale	Whole group	Healthy subjects	CV group	Functional group
(0 to 7)	(n=30)	(n=10)	(n=10)	(n=10)
No (<4)	11 (36.66%)	1 (10%)	5 (50%)	5 (50%)
Middle (=4)	1 (3.33%)	1 (10%)	0	0
Yes (>4)	18 (60%)	8 (80%)	5 (50%)	5 (50%)

Table 7: Motive related to Competence/Challenge. Prevalence and strength of this motive in the whole group and in separated groups. Results are expressed by the number of subjects and the related percentage.

Social (which refers to being physically active in order to be with friends and meet new people) (Table 8). These results seem to be more various, as only half of the healthy subjects and cardiac patients are based on this motive to practice a physical activity. In the functional group, 70% of the patients declared to be concerned by the social component of the physical practice. Please note that few patients of this group had a stroke and were quite limited in physical abilities and usual social contacts. However, in regards to these results, it might be hypothesized that a PAMAP device used at home may not disrupt a lot of patients (of course, social contacts must be preserved as the social isolation is an important risk in ageing populations). Sharing data using PAMAP device might also participate to the social dimension of the physical activity, as the physician could regularly follow how the subject is practicing alone at home, and modify his (her) physical program when needed (quick feed-back).

Scale	Whole group	Healthy subjects	CV group	Functional group
(0 to 7)	(n=30)	(n=10)	(n=10)	(n=10)
No (<4)	11 (36.66%)	5 (50%)	4 (40%)	3 (30%)
Middle (=4)	2 (6.66%)	0	1 (10%)	1 (10%)
Yes (>4)	18 (56.66%)	5 (50%)	5 (50%)	7 (70%)

Table 8: Motive related to Social. Prevalence and strength of this motive in the whole group and in separated groups. Results are expressed by the number of subjects and the related percentage.

Enjoyment (which refers to being physically active just because it is fun, makes you happy, and is interesting, stimulating, and enjoyable) (Table 9). This motive tends to show how pleasant must be a PAMAP device. Indeed, enjoyment is a strong motive for physical practice, in all healthy subjects but also in 80% of the patients.

Scale	Whole group	Healthy subjects	CV group	Functional group
(0 to 7)	(n=30)	(n=10)	(n=10)	(n=10)
No (<4)	2 (6.66%)	0	1 (10%)	1 (10%)
Middle (=4)	2 (6.66%)	0	1 (10%)	1 (10%)

Yes (>4)	26 (86.66%)	10 (100%)	8 (80%)	8 (80%)
----------	-------------	-----------	---------	---------

Table 9: Motive related to Enjoyment. Prevalence and strength of this motive in the whole group and in separated groups. Results are expressed by the number of subjects and the related percentage.

All other questionnaires are under treatment and no further results could be currently communicated.

In addition to the initial qualitative comments, suggestions, and feedback summarized above, evaluations on basis of the collected data will drive further developments, also in follow-up projects, and provide material for joint publications. One concrete example of a PAMAP follow-up project is the project ActivityPlus, which started in May 2012 and is financed by the Stiftung Rheinland-Pfalz für Innovation. The goal in ActivityPlus is to develop more complex and personalized algorithms for physical activity monitoring, which will be evaluated using the rich datasets collected in the PAMAP project. The consortium shares the strong wish to continue the collaboration in the future, also beyond the PAMAP project.

Moreover, the datasets recorded in the Aerobic Activity Monitoring use case of the PAMAP project have been made publicly available for research purposes, and can be downloaded from the project's website (http://www.pamap.org/demo.html). Since there is a lack of a commonly used, standard dataset in the research field of physical activity monitoring, researchers of this field show great interest in using the PAMAP datasets to test their methods and validate their work, and state that releasing the datasets is a great service to the research community. The first dataset was released in June 2011, and was presented at the "Workshop on Robust machine learning techniques for human activity recognition", hosted at IEEE SMC'11 conference. The second dataset was released in January 2012, and was presented - together with a benchmark on the dataset, including data recorded during the clinical trials, home phase. Despite the only recent publication of these datasets, there is already one publication using them by a research group (the Department of Computer Science and Engineering, University of California, Riverside) outside of the consortium: T. Rakthanmanon, E. J. Keogh, S. Lonardi, and S. Evans. MDL-based time series clustering. *Journal of Knowledge and Information Systems*, Springer, 2012.

As for the Aerobic Activity Monitoring use case, it is also planned to make the dataset recorded during the strength exercise monitoring use case publicly available for research purposes. A publication presenting the dataset together with results from the developed motion pattern learning and segmentation algorithms was accepted at ICPR 2012 and the dataset is currently already used for teaching activities at the university.

5 APPENDIX

The following documents (as referenced above) provide additional information and technical details. Please note that some of these documents are coming from a research office of the hospital and are therefore confidential:

The entire appendix is only listed in this file. They are joined separately to this report.

- Appendix 1: Ethics committee agreement (Appendix1_EthicsCommitteeAgreement.pdf)
- Appendix 2: AFSSAPS agreement (AFSSAPS: Agence Française de Sécurité SAnitaire des Produits de Santé) (Appendix2_AFSSAPSAgreement.pdf)
- Appendix 3: Pictures of the exercises panel (Appendix3_ExercisePanel.pdf)
- Appendix 4: Exercises naming (Appendix4_ExerciseNaming.pdf)
- Appendix 5: Technical summary of the hospital phase protocol (Appendix5_Trials_Phase2_Protocol)
- Appendix 6: French translated questionnaire on the User Interface developed in WP5 for evaluating the usability of the system (Appendix6_Questionnaire_UserInterface.pdf),
- Appendix 7: Socio-cognitive questionnaires (Appendix7_SocioCognitiveQuestionnaires.pdf)
- Appendix 8: Technical description of the protocol related to home monitoring (Appendix8_Trials_Phase1_Protocol.pdf)
- Appendix 9: PAMAP hardware sets-up for home monitoring (Appendix9_PAMAP_HW_HomeTrials.pdf)
- Appendix 10: Daily Health Profile, Dartmouth and QLMI2 surveys (Appendix10_HealthProfile_Surveys.pdf)
- Appendix 11: Example of an accurate physical activity notebook in a cardiovascular patient (Appendix11_PANotebook.pdf)
- Appendix 12: One completed case report form (Appendix12_CaseReportForm.pdf)
- Appendix13: PAMAP tutorial for hospital trials (Appendix13_Tutorial.pdf)