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Project coordinator: Poznań Supercomputing and Networking Center, ul. Jana Pawła II 10, 61-139 Poznań, Poland, email: fit4work@fit4work-aal.eu



# Pilot Trial Methodology

Ambient Assisted Living Joint Programme project no. AAL-2013-6-060 Deliverable 2.4, version 1.2

Lead author: Marije Blok, KBO-PCOB

Co-authors: Christien Müskens KBO-PCOB

Nora Ramadani, KBO-PCOB Jan Brinkers, KBO-PCOB

Michał Kosiedowski, Poznań Supercomputing and Networking Center

Robert Szeklicki, Poznań University of Physical Education

Božidara Cvetković, Jožef Stefan Institute

Project coordinator: Poznań Supercomputing and Networking Center, ul. Jana Pawła II 10, 61-139 Poznań, Poland, email: fit4work@fit4work-aal.eu

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Published on 24th of May 2016

Current revision published on 26<sup>th</sup> of July 2017

The Fit4Work project is co-financed through the AAL Joint Programme by:

- European Commission
- National Centre for Research and Development, Poland
- Ministry of Industry, Energy and Tourism, Spain
- Executive Agency for Higher Education, Research Development and Innovation Funding, Romania
- Ministry of Higher Education, Science and Technology, Slovenia
- The Netherlands Organisation for Health Research and Development (ZonMW), The Netherlands



# **Table of contents**

1.		Intro	oduct	ion	7
2.	1	Aim	s of a	ssessment	8
	2.1	l.	Asse	essment objectives	8
	2.2	2.	Para	meters of success	8
	:	2.2.	1.	Quality of life of end users (Quantitative)	8
	:	2.2.	2.	Health-related fitness (H-RF) of end users (Quantitative)	8
	:	2.2.	3.	Physical activity of end users (Quantitative)	9
	:	2.2.	4.	Project acceptance by end users (Qualitative)	9
	:	2.2.	5.	System usability (Qualitative)	9
	:	2.2.	6.	Perceived stress (Quantitative)	9
	:	2.2.	7.	Perceived quality of environment (Quantitative)	9
3.		Plan	ning	of the pilot field trials	10
4.	1	First	pilo	t trial: part of user-centric development	11
	4.1	l.	Aim		11
	4.2	2.	Sett	ing	11
	4.3	3.	Reci	uitment of participants	11
	4.4	l.	Prot	ocol for testing	12
		4.4.	1.	Planning	12
		4.4.	2.	Training	12
		4.4.3	3.	Tools and Instruments for testing	12
5.		Seco	ond p	ilot trial: validation of the developed solution	13
	5.1	L.	Aim		13
	5.2	2.	Sett	ing	13
	5.3	3.	Reci	ruitment of participants	13
	!	5.3.:	1.	The Netherlands	13
	!	5.3.	2.	Poland	13
	5.4	l.	Prot	ocols for testing	13
	!	5.4.:		Planning	
	ļ	5.4.	2.	Tools and instruments for testing	
6.		Bibli	iogra	phy	
Ar				med consent	

Project coordinator: Poznań Supercomputing and Networking Center, ul. Jana Pawła II 10, 61-139 Poznań, Poland, email: fit4work@fit4work-aal.eu

Annex B. Evaluation tools	18
B.1. Baecke questionnaire for the evaluation of physical activity	18
Scoring	20
B.2. Perceived Stress Scale (PSS)	21
Scoring	21
B.3. WHOQOL-BREF Questionnaire	22
Scoring	24
B.4. Perceived ambient conditions	25
Scoring	26
B5. System usability scale	27
Scoring	27



#### 1. Introduction

The Fit4Work project aims to develop a system that enables persons aged 55 and over to be healthy and maintain good functional capacities for work. In this way the project answers the need to facilitate continuation of professional careers, making ageing workers aware of a better transition into 'golden years' of their work span and prepare enterprises to develop their work environments with age-related issues incorporated into the frame of their business.

Previously in the project, usability requirements were defined. By means of an extensive internationally distributed survey, literature research, interviews and a focus group session we identified the preferences, needs and expectations of the prospect end-users. Topics included 1) the device(s) to be used; 2) the kind of information to be monitored with the product (what is possible, what is desirable?); 3) use(r)-related factors, concerning both characteristics of the device and the user; 4) the setting in which the product can be used and 5) privacy related issues. This resulted in a document with end-user requirements, categorized in the mentioned topics.

The present document aims at defining the guidelines for the different pilot testing phases. The standard protocols for testing the Fit4Work system across the whole validation phase are described herewith.

The pilot testing will take place in two stages:

- 1. In the first stage an early prototype will be tested by 8 test-users in the Netherlands. The aim of this first explorative stage of evaluation is to discover the usability of the Fit4Work system among a variety of users in the actual field setting in which the end solution developed by the project is foreseen to be used. This stage will run in parallel with the system developments, therefore its critical aspect is to ensure a proper communication channel or protocol between the test users and the developers. This first stage of evaluation will take 2 months.
- 2. The final prototype of the system will be tested in the second pilot trial the validation stage, which takes place at the end of the project. The pilots within this trial will take place in different settings, in the Netherlands (organized by KBO-PCOB) and Poland (organized by PSNC). This allows the consortium to test the prototype among different groups of older adults. Paid and voluntary workers will test the prototype at both the desk work and physical active work setting. The aim of this validation stage is to find out whether the project was successful in developing useful and functional solution for managing their physical and mental fitness.

The report presents the aims of assessment of the solution developed within the project in Section 2. The planning of the solution piloting is discussed in Section 3 (general planning) and Section 4 and 5 (pilot 1 and 2 respectively). Discussion on usability and acceptance testing is presented in Section 6. The report ends with annexes containing the informed consent template and questionnaire tools to be used during assessments.

#### 2. Aims of assessment

### 2.1. Assessment objectives

The general scope of the assessment is to gain a high level of compatibility of the Fit4Work system with users' expectations and needs both from a usability and functional point of view in line with an incremental user-centric development methodology. The conformance of the usability and functionality of the product to users' requirements will be evaluated in order to have an early feedback about the system function, its acceptability and usability from an older adult viewpoint and the system will be constantly re-adapted to meet their requirements.

Another objective of the evaluation process is to provide organizations with an innovative easy-to-use and unobtrusive system that will support older workers in reducing and managing physical and mental stress resulting from their occupation. The system will provide ambient ways of monitoring physical and mental activities at work. Smart algorithms will provide context-sensitive personalized recommendations for adjusting the workplace and behavior at work, as well as define lifestyle plans to meet the demands of the work taking into consideration the worker's age. The currently described assessment will help to deliver a system which perfectly meets the preferences of the prospect client.

The specific objectives of the assessment are strictly connected with the level of development of the product. As assessments will be implemented alongside the project, we need to make certain that there is significant synergy between the scopes of assessment across the several evaluations using a similar methodology.

For this reason, the general evaluation procedure described in this deliverable provides a consistent basis for the setting down of our framework methodology for the following assessments. At the same time, this procedure will be better specified in the following deliverables of WP2 in close relation with the testing activities we will run along WP2 and the correspondent level of the development of the product. The specific objectives of each evaluation will be better defined and some description of variables to assess will be provided.

#### 2.2. Parameters of success

The success of the project should be measured on several layers. These layers include, among others, a variety of aspects concerning the use(r) of the system; publicity for the concept and dissemination. First, the system will be tested and validated at supporting end-users in improving specific aspects of their lives (WHOQOL, H-RF, Physical activity, PSS and Environment). Next the technology developed by the project should be accepted and usable by the prospect end-users (Acceptance & Usability).

#### 2.2.1. Quality of life of end users (Quantitative)

- **Description:** Increase of Quality of Life of the end-users taking advantage of the system
- Method of verification: WHOQOL instrument before and after using the Fit4Work system
- Target: End users increase quality of their lives according to the WHOQOL

#### 2.2.2. Health-related fitness (H-RF) of end users (Quantitative)

• **Description:** H-RF refers to those components of fitness that are affected by habitual physical activity and relate to health status



- Method of verification: Senior Fitness Test
- Target: at least 75th percentile (with relation to age and gender of the actual end-user)

#### 2.2.3. Physical activity of end users (Quantitative)

- **Description:** Every movement of the body caused by skeletal muscle and related with energy expenditure above the resting metabolic rate
- Method of verification: average daily energy expenditure
- Target: 200 kcal/day

#### 2.2.4. Project acceptance by end users (Qualitative)

- **Description:** Project design should answer the needs of the end users
- **Method of verification:** Verification of the user requirements, system specification with different groups of end users
- **Target:** User requirements recognized by end users survey (50 person per country), by feedback from end users experts, by pilot trials

#### 2.2.5. System usability (Qualitative)

- Description: Realization of end-user needs in an effective, efficient, satisfactory way
- Method of verification: Usability assessment by end-user feedback reception through interviews, surveys, end-user direct observation, monitoring in different cycles of project development – developments, tests, deployments
- Target: High usability of the system proven by the feedback from end-users

#### 2.2.6. Perceived stress (Quantitative)

- Description: The degree to which situations in one's life are appraised as stressful
- Method of verification: Average score on the PSS-scale before and after using the system
- Target: End users will decrease their level of perceived stress after using the system

#### 2.2.7. Perceived quality of environment (Quantitative)

- **Description:** The degree to which the environment is perceived as comfortable
- Method of verification: Average score on the Environment scale before and after using the system
- Target: End users will increase their level of perceived environmental comfort after using the system

### 3. Planning of the pilot field trials

The Fit4Work system will be tested and validated within two consecutive stages of field trial.

In the **first stage of piloting an early prototype will be tested**. This first phase will be mainly explorative and will take place without a structured protocol and without the use of standardized questionnaires. This stage of validation will take two months. Every month the users' feedback will be collected and presented in a feedback summary. This will result in an interactive cooperation between the process of technical development and the experience of end-users.

The aim of the **second stage is validation of the end solution**. Therefore its goal is to measure the project success in the Fit4Work system development, on the basis of the defined parameters of success (see paragraph 2.2). This second and final evaluation stage will take 1 month and take place according to a detailed protocol. Along the way, two interim reports will be delivered with results of the tested parameters.

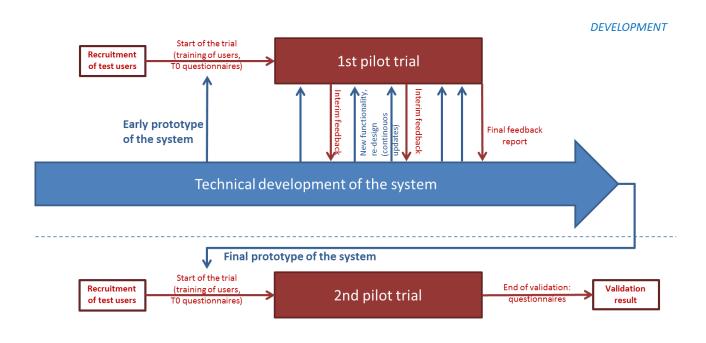


Figure 3.1. Planning of the Fit4Work pilot trials

**VALIDATION** 



### 4. First pilot trial: part of user-centric development

#### 4.1. Aim

The aim of this first explorative stage of is to find the start-up problems of the Fit4Work system and to measure the user experience of the early prototype. Therefore the focus in this stage will mainly be on the usability, rather than on (quantitative) health and fitness outcomes. The findings of this early test stage will function as an input to the technical development of the system taking place in parallel to the field trial of the early prototype. Not only feedback concerning experience is gained, but it is also an advantage to getting more insight in desires of end-users. This phase and method of gaining information allow the developers of the system to receive valuable feedback which they are unable to receive when working only in the laboratory settings.

### 4.2. Setting

The trial in this first stage will take place in the Netherlands. For this trial a selection of 8 test-users was made. As Fit4Work focuses on persons aged 55 and up, with a paid or voluntary job (or other structural activities like providing informal care) in which they (may) experience (physical or mental) stress, the selection was based on those criteria. When someone's job mainly consists of desk activities, the focus will be on the right sitting posture, promotion of physical activity and prevention of mental stress; when a job primary includes physical activities, special attention will be paid on total body postures and lifting loads.

Table 1 Participants of first validation stage

Description of participant	Age	Location	N
Older adult with a desk job, executing office activities	55-65	The Netherlands (KBO-	7
		PCOB)	
Elderly person with a voluntary desk job, executing	65-75	The Netherlands (KBO-	1
office activities		PCOB)	
		Total amount of participants	8

#### 4.3. Recruitment of participants

Participants will be recruited among the members, elderly employees and their social network of KBO-PCOB. In the previous phase, a survey was distributed among the prospect users and filled in by 67 Dutch respondents, aged 50-75 years old. Several of them mentioned that they would like to stay involved in the project. Some of them also attended the focus group session, in which the users' preferences were discussed more in depth.

The approached persons that are interested in taking part in the field trials and meet the criteria will be selected to participate in the field trials. In the invitation, the procedures of the trials will be described (see Appendix), as well as the profiles of the preferred participants.

### 4.4. Protocol for testing

#### 4.4.1. Planning

Date	Activity	Deliverable	Т
March 2017	Recruitment of test-users early		
	trials according to recruitment		
	strategy		
May 2017	Start trials of the early		T0
	prototype in the Netherlands:		
	<ul> <li>Kick-off meetings with all</li> </ul>		
	participants with:		
	* Introduction / training		
	* Signing of Informed Consent		
	* T0 Questionnaires		
June 2017	First feedback from test-users	D2.5.1A	T1
	early trials		
July 2017	Second feedback from test-	D2.5.1B	T2
	users early trials		
August 2017	Integration of feedback of early	D2.5.1 Feedback from	T4
	trials in final report	first cycle of validation	

#### **4.4.2. Training**

An introductory training will be organized to equip the test-users with the Fit4Work system before they start. This training will allow the participants to ask questions and to test whether the prototype works properly. The training will be organized by KBO-PCOB, which is in charge for test sessions. The trainer will be previously equipped with relevant instructions prepared by technical partners, as well as will undergo basic training on how to install and technically maintain the system.

#### 4.4.3. Tools and Instruments for testing

As mentioned, this first stage of validation will take place without a structured protocol. Since the aim of this phase is to collect both data and clues for further development and research, the test-users need to get space to share their thoughts concerning any topic. Only several standardized questionnaires will be used to gather background information about the test-users.

The following instruments will be used in the first phase (in order in which they will be used):

- Questionnaire personal background characteristics (T0)
- Aptitude for usage Questionnaire (T0)



### 5. Second pilot trial: validation of the developed solution

#### **5.1.** Aim

The aim of the second stage of evaluation is to measure the success of the developed Fit4Work solution. This evaluation of parameters concerns only the layers that are related to the use(r), since this is investigated in the pilots. Parameters concerning innovation, business, dissemination and project management will be evaluated separately, since these are not directly related to the use of the product.

### 5.2. Setting

The pilots in this second evaluation stage will take place in two countries: the Netherlands and Poland. The system will be tested by 10 participants in the Netherlands and 10 in Poland. Because the aim is to test the system in a real life environment, the chosen setting was to test the system in how it is expected to be used: by people during their work. Because of the time limit and practical reasons, as many participants in one office were desired in which the participants had different functions and activities. Both participants with stationary as physical work activities were included.

### 5.3. Recruitment of participants

#### **5.3.1.** The Netherlands

As the amount of participants in the Netherlands was rather small, participants that meet the criteria were therefore easy to find. Through announcement in the organization different people showed interest in the project themselves. As for practical reasons participants were selected that worked nearby each other, so that a bigger group could take part of the test taking at once. Another notion was to include both stationary as physical work in the study.

#### **5.3.2.** Poland

The recruitment of pilot trial participant was done with the support of the Poznan City Hall. It was proposed to recruit pilot users from the community of nurses and professional caregivers working at elderly care homes maintained by the Poznań City.

### 5.4. Protocols for testing

### 5.4.1. Planning

Date	Activity	Deliverable
October 2017	Recruitment of test-users	
	according to recruitment strategy	
November 2017	Start trials pilot in Poland and the	
	Netherlands:	
	- Kick-off meetings with all	
	participants of three settings	
	with:	
	* Introduction	
	* Training	

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	* Signing of Informed Consent	
	* T0 Questionnaires	
End November	First feedback from test-users	D2.5.2A
2017		
Begin	Second feedback from test-users	D2.5.2B
December 2017		
End December	Integration of feedback of pilots	D2.5.2 Verification of
2017	in final report and evaluation of	the system against
	additional success parameters	success parameters

#### 5.4.2. Tools and instruments for testing

At the beginning of this pilot, the separate groups of participants in the pilot are invited for an introduction kick-off session. A presentation will be given about the project, the Fit4Work system and the pilot in which the test-users participate. Next to that, the participants get the opportunity to ask questions. In this introduction session, the participants also will be asked to sign an informed consent in their own language (see Annex A). After that, participants need to fill in the questionnaire (see Annex B for particular questionnaire tools to be used) and perform the Functional Fitness Test. In the end, the participants will receive the materials and will try out the system. They are asked to execute different tasks and to test the different functionalities of the system. Also, it is possible to contact the project leader when experiencing problems with the system.



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#### Annex A. Informed consent

The present document is composed in two sections, information sheet and declaration. The information sheet explains the activities that are going to take place today, and the statement – if signed- is your consent to participate in these activities. We invite you to read the document carefully and, if you need to, to ask for clarifications before signing it.

#### Information sheet

The data collection will be carried out by the staff of [insert research institution name] and particularly by [insert researchers' names] today [insert date] at [insert place] for the Fit4Work project.

The activity that constitutes this data collection is composed by:

- A questionnaire
- Doing a physical test

The data gathered (questionnaire, informed consent and video) will be archived, protected and handled by KBO-PCOB in compliance with the present information sheet, and under the European Union regulation on data protection (Directive 95/46/EC e 2002/58/EC). To access to the anonymous data and to the videos will be possible exclusively to the member of the Fit4Work project. The researchers commit to preserve your anonymity and the anonymity of other people or institutions to whom you might refer to during the data collection.

The research results will be made public through scientific papers, conferences and events with education purposes only.

The data collected will be used for research purposes and can be shared among the members of the Fit4Work consortium.

If you are interested in the research result – at the end of the study- you are free to contact Nora Ramadani.



	Declaration
Name	Surname
ID	
Date of birth	
□ female □ male	
written in this document and agrees to operating at the vest of his/her abilities a	name] declares to have read and understood all the information take part to the data gathering therein described on [insert date] and truthfully answering to all questions.  Greement impedes the participation in the data collection).
Date	Participant's signature
- , ,	name] accepts that his/her images extracted from the videothe results of Fit4Work (The refusal to underwrite this second participation in the data collection).
Date	Participant's signature

.....

.....

### **Annex B. Evaluation tools**

# B.1. Baecke questionnaire for the evaluation of physical activity

1.Wha	at is your main occu	pation?					
	Study		1				
	Household		3				
	Work		5				
			Never	Seldom	Sometimes	Often	Always
2. At v	vork I sit (5,4,3,2,1)						
3. At v	vork ا stand (1,2,3,4	<b>1,</b> 5)					
4. At v	vork I walk (1,2,3,4	,5)					
5. At v	vork I lift heavy load	s (1,2,3,4,5)					
6. At v	vork I am tired (1,2	,3,4,5)					
7. At v	vork I sweat (1,2,3,	4,5)					
8. In c	omparison with oth	ers of my own a	ge I think my v	work is physi	cally (5,4,3,2,1	.)	
_	Much heavier	Heavier	As hea	avy	Lighter	Much ligh	ter
	you play sport? es □ No □ <u>(go (</u>	on to question 16	<u>5)</u>				
10. If	yes, which sport do	you play most fr	equently? (1,3	3,5)			
11. Ho	ow many hours a we	e <b>k?</b> (1,2,3,4,5)					
_	<1	1 to 2	2 to	3	3 to 4	4+	



<b>18.</b> During leisure time	.During leisure time I play sport (5,4,3,2,1)									
17.During leisure time,	7. During leisure time, I sweat (5,4,3,2,1)									
		Always	Often	Sometimes	Seldom	Never				
			[							
16. In comparison with others of my own age I think my physical activity during leisure time is active (5,4,3,2,1)  Much more More The same Less Much less										
<1	1 à 3	4 à 6		7 à 9	10 à 12	<u>!</u>				
15. How many months	s a year? (1,2,3,4,5)									
<1	1 à 2	2 à 3		3 à 4	4+					
14. How many hours a week? (1,2,3,4,5)										
13. If you play a second sport, which sport is it? (1,3,5)										
<1	1 to 3	4 to 6		7 to 9	10 to 1	2				
12. How many months										

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		Never	Seldom	Sometimes	Often	Always
19. During leisure time I watch tele	vision					
(5,4,3,2,1)			<u></u>		<u> </u>	
<b>20.</b> During leisure time I walk (1,2)	3,4,5)					
21. During leisure time I cycle (1,2	,3,4,5)					
	(in minute:	<u>s)</u> <5	5 – 10	0 15-30	30 – 45	45+
22. How many minutes per day do	you walk and/o	or				
cycle to and from work, school (1,2,3,4,5)	and shopping	35 □				
Scoring  If type of sport = 1 then intensity = .76  3 = 1.26  5 = 1,76	Simple Sport S (intensity*time (intensity*time 0 is given to pe	e*proportic e*proportic	on)+ on)=0/0.01-	-<4/4-<8/8-<12 sport.	/12	
If number of hours a week =<1 then Time = .5						
1-2 = 1.5 2-3 = 2.5	Work index	(1+2+3+4	+5+6+7+8),	/8		
4-5 = 3.5	Sport index	([9-15]+1	6+17+18)/4	1		
>4=4.5	Leisure time	(19+20+2	1+22)/4			
If number of months a year = <1 then proportion .04 1-3 = 0.17 4-6 = 0.42 7-9 = 0.67 >9 = 0.92	Total index	Work index	ex + sport i	ndex + leisure 1	ime	



# **B.2. Perceived Stress Scale (PSS)**

In the last month	Never	Almost	Sometimes	Fairly often	Very
		never			often
1 how often have you been upset					
because of something that happened					
unexpectedly?					
2 how often have you felt that you					
were unable to control the important					
things in your life?					
3 how often have you felt nervous					
and 'stressed'?					
4 how often have you felt					
confident about your ability to					
handle your personal problems?					
5 how often have you felt that					
things were going your way?					
6 how often have you found that					
you could not cope with all the					
things that you had to do?					
7 how often have you been able to					
control irritations in your life?					
8 how often have you felt that you					
were on top of things?					
9 how often have you been					
angered because of things that were					
outside of your control?					
10 how often have you felt					
difficulties were piling up so high					
that you could not overcome them?					

### **Scoring**

	Never	Almost never	Sometimes	Fairly often	Very often
Q.1,2,3,6,9,10	0	1	2	3	4
Q.4.5.7.8	4	3	2	1	0

# **B.3. WHOQOL-BREF Questionnaire**

1. How would you rate your Quality of Life?

Very poor				٧	ery good		
1	2	3	4		5		
2. How satisfied are	you with your heal	th?					
Very dissatisfied				Ve	ry satisfie	ed	
1	2	3	4		5		
The following quest	ions ask about <b>how</b>	much you have experier	nced certai	n things i	n the last	four wee	eks.
			Not at al		An ex	treme ar	mount
			1	2	3	4	5
3.To what extent do	you feel that physi	cal pain prevents you	П	П	П		
from doing what yo	u need to do?						
4.How much do you	ı need any medical t	reatment to function in		П	П		
your daily life?							
5.How much do you	ı enjoy life?						
6.To what extent do	you feel your life to	o be meaningful?					
7.How well are you	able to concentrate	?					
8.How safe do you	feel in your daily life	?					
9.How healthy is yo	ur physical environr	ment?					
10.Do you have end	ough energy for ever	yday life?					
11.Are you able to a	accept your bodily a	ppearance?					



12. Have you enough money to meet your needs?							
13.How available to y		П					
your day-to-day life?			Ш	Ш			ш
14.To what extent do	you have the opp	ortunity for leisure					
activities?			Ш	Ш	Ш	Ш	Ш
15.How well are you	able to get around	?					
Very poor	Neither poor nor g	ood	Good		Very good		
			Very dis	satisfied		Very sa	tisfied
			1	2	3	4	5
16.How satisfied are	you with your slee	ep?					
17. How satisfied are you with your ability to perform your							
daily living activities	?						Ш
18.How satisfied are	you with your cap	pacity for work?					
19.How satisfied are	you with yourself	?					
20.How satisfied are	you with your per	rsonal relationships?					
21.How satisfied are	you with your sex	life?					
22.How satisfied are	you with the supp	oort you get from your		П		П	
friends						ш	
23. How satisfied are you with the conditions of your living							
place?						Ш	
24.How satisfied are	you with your acc	ess to health services?					
25. How satisfied are you with your transport?				П		П	

Project coordinator: Poznań Supercomputing and Networking Center, ul. Jana Pawła II 10, 61-139 Poznań, Poland, email: fit4work@fit4work-aal.eu

25. How often do you have negative feelings such as blue mood, despair, anxiety, depression?

Never	Seldom	Quite often	Very often	Always	

### **Scoring**

	Equations for computing	Daw scare	Transfo	ormed scores*
	domain scores	Raw score	4-20	0-100
Domain 1	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18	=	b:	C:
Domain 2	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26)	=	b:	C:
Domain 3	Q20 + Q21 + Q22	=	b:	C:
Domain 4	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25	=	b:	c:

<sup>\*</sup>To convert raw scores into transformed scores, Table 4 in WHOQOL-Bref is used.



### **B.4. Perceived ambient conditions**

		5	4	3		
	COMFORT FACTOR	Strongly agr	gree Strongly dis		ngly disa	gree
	LIGHTING					
1.	The lighting is suitable and does not influence my posture					
2.	The lighting is too bright to work comfortably					
3.	The lighting is too dim to work comfortably					
4.	The computer monitor is placed so that light from					
	windows and overhead lighting does not cause glare					
	TEMPERATURE					
5.	The ambient temperature is comfortable					
6.	The temperature in the workplace does not fluctuate					
	during a normal working day					
7.	The ambient temperature is too hot					
8.	The ambient temperature is too cold					
	NOISE					
9.	The level of noise is comfortable					
10	The level of noise does not affect concentration					
11.	The level of noise allows conversation and other					
	communication without significant effort					
12.	There are sources of uncomfortable equipment noise					
	AIR QUALITY					
13.	The air feels comfortable					
14.	The air circulation is comfortable					
15.	Warm air is not blowing directly into the workspace					
16.	Cold air is not blowing directly into the workspace					
17.	The air quality is satistactory					
18.	The air is too dry					
	WORK TYPE					
19.	Your work is mainly sedentary					
20.	Your work involves moderate physical activity					
21.	Your work involves intense physical activity					

### Scoring

Question	Score	
1	5/4/3/2/1	
2	1/2/3/4/5	reverse coding!
3	1/2/3/4/5	reverse coding!
4	5/4/3/2/1	
5	5/4/3/2/1	
6	5/4/3/2/1	
7	1/2/3/4/5	reverse coding!
8	1/2/3/4/5	reverse coding!
9	5/4/3/2/1	
10	5/4/3/2/1	
11	5/4/3/2/1	
12	1/2/3/4/5	reverse coding!
13	5/4/3/2/1	
14	5/4/3/2/1	
15	5/4/3/2/1	
16	5/4/3/2/1	
17	5/4/3/2/1	
18	1/2/3/4/5	reverse coding!
19	1/2/3/4/5	reverse coding!
20	5/4/3/2/1	
21	5/4/3/2/1	



# **B5. System usability scale**

	Strongly disagree → Strongly agree				agree
	1	2	3	4	5
1.I think that I would like to use this system frequently.					
2.I found the system simple.					
3.I thought the system was easy to use.					
4.I think that I would not need the support of a technica person to be able to use this system.					
5.I found the various functions in this system were wel integrated.					
6.I thought there was much consistency in this system.					
7.I would imagine that most people would learn to use this system very quickly.	· 🗆				
8.I found the system very cumbersome to use.					
9.I felt very confident using the system.					
10.I could use this system without learning new things.					

### **Scoring**

	Strongly	Disagree	Neutral	Agree	Strongly
	disagree				agree
All questions	1	2	3	4	5