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D.3.2. Sensors and Aggregators for Personal Sensor Data

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Executive Summary

This deliverable contains detailed information on sensors used for the acquisition of personal data as well as appropriate data aggregator architecture and implementation. After previous analysis of observables and data sources needed for monitoring of personal health data of patients having cardiorenal risks the most suitable sensor candidates from the market were selected. Four groups of monitoring sensors – for weight and body composition; for physical activity; blood glucose measurement; and cardiovascular state were tested and evaluated with the aim to compare testing results and to recommend the most reliable, unobtrusive, accurate and software-friendly ones for the use of patients in pilot sites. Since commercially available sensors do not cover fully all monitoring requirements, results of investigation of possibilities to develop new sensors and algorithms were presented as well. Among new developments is wristwatch for continuous monitoring of health parameters, an innovative algorithm for arrhythmia detection and smart scales for integration of all sensor data into CARRE semantic repository using cloud services was developed and details of implementation presented.

About CARRE

CARRE is an EU FP7-ICT funded project with the goal to provide innovative means for the management of comorbidities (multiple co-occurring medical conditions), especially in the case of chronic cardiac and renal disease patients or persons with increased risk of such conditions.

Sources of medical and other knowledge will be semantically linked with sensor outputs to provide clinical information personalised to the individual patient, so as to be able to track the progression and interactions of comorbid conditions. Visual analytics will be employed so that patients and clinicians will be able to visualise, understand and interact with this linked knowledge and also take advantage of personalised empowerment services supported by a dedicated decision support system.

The ultimate goal is to provide the means for patients with comorbidities to take an active role in care processes, including self-care and shared decision-making, and also to support medical professionals in understanding and treating comorbidities via an integrative approach.



Terms and Definitions

The following are definitions of terms, abbreviations and acronyms used in this document.

Term	Definition
AAMI	Association for the Advancement of Medical Instrumentation, is a nonprofit organization founded in 1967. Mission - supporting the healthcare community in the development, management, and use of safe and effective medical technology.
Accuracy	According to ISO 5725-1, Accuracy consists of Trueness (proximity of measurement results to the true value) and Precision (repeatability or reproducibility of the measurement)
AF	Atrial Fibrillation
AHI	Apnea-hypopnea index
API	Application Programming Interface
BHS	British Hypertension Society
BIA	Bioelectrical Impedance Analysis
BIS	Bioelectrical Impedance Spectrography
BIVA	Bioelectrical Impedance Vector Analysis
BLE	Bluetooth Low Energy
BP	Blood Pressure
BPM	Blood Pressure Monitor
Data source	Devices and sensors (e.g. weight scales, physical activity monitors), personal health record, electronic medical record, personalized information on lifestyle (e.g. Facebook, Twitter), sources of medical evidence and other medical authoritative information (e.g. PubMed), on-line patient educational sources (e.g. MedlinePlus)
Diastolic BP	Diastolic blood pressure – lower of the two numbers which shows the pressure in the arteries when the heart muscle is resting between beats and refilling with blood.
ECG	Electrocardiogram – graphical representation of electrical cardiac activity registered by using biopotential electrodes.
ESH	European Society of Hypertension
GET	HTTP method
GPS	Global Positioning System
HTTP	Hypertext Transfer Protocol
IPG	Impedance plethysmogram – graphical representation of mechanical cardiac activity registered by sensing impedance changes.
JSON	JavaScript Object Notation
LCD	Liquid Crystal Display
MET	Metabolic equivalent
NIBP	Noninvasive blood pressure. Mostly measured by two methods: auscultatory (manual), oscillometric (automatic)
Observable	Physical variable that can be measured or otherwise ascertained (e.g. biomarkers, biometric variables, biological signals and other non-biological factors e.g. environmental).
OGTT	Oral Glucose Tolerance Test



PAF	Paroxysmal atrial fibrillation is an episode of uncoordinated movement of the cardiac atria and irregular heart that occurs occasionally and then stops. Episodes can last from minutes to days before stopping and returning to normal "sinus" rhythm.
PAT	Pulse arrival time is associated with pulse wave velocity and is defined as the time interval between the R-wave of the QRS complex in the electrocardiogram and the particular point in the pulse pressure wave recorded at the distal artery.
PC	Personal Computer
POST	HTTP method
PPG	Photoplethysmogram - graphical representation of mechanical cardiac activity registered by using optical sensor.
PVC	Premature Ventricular Contraction
RDF	RDF (Resource Description Framework) is a standard model for data interchange on the Web.
Systolic BP	Systolic blood pressure – higher of the two numbers, which shows the pressure in the arteries when the heart muscle contracts.
SPARQL	An RDF query language. http://www.w3.org/2009/sparql/
SD	Standard deviation of measurements.
TBW	Total body water
URL	Uniform Resource Locator, a.k.a. a web address



1. Introduction

This document is a report of the project Task 3.2 "Sensors and Aggregators for Personal Sensor Data". It is based on previous project deliverables:

- D.2.2 "Functional Requirements & CARRE Information Model", where patient risks and needed observables were analyzed and classified from the point of view of medical domain specifics and CARRE information model;
- D.2.3 "Data source identification and description", where data sources were analyzed and review of all available appropriate sensors presented; and
- D.3.1 "Aggregator Module Generic Design", where the concept of data aggregation of all data sources including personal sensors is presented.

The aim of Task 3.2 is to determine an appropriate set of sensors, evaluate their accuracy, reliability, robustness and security using testing results of available 3rd party candidates as well as to capture the semantics of monitoring data, i.e. to ensure semantic sensors data linking and aggregation into CARRE data repository. Section 2 of this report present testing and evaluation of selected 3rd party sensors and conclusions regarding their characteristics and applicability. Section 3 investigates possibilities to develop new sensors and algorithms needed to cover specific needs of monitoring which are not covered by commercially available sensors and also for data aggregator architecture and cloud services as well as for implementation issues. Finally, Section 4 presents the details of the development and implementation of the aggregators for the selected sensors.

Annex 1 gives links for downloading the actual D.3.3 deliverable which is the sensor aggregator software developed in T.3.2 (and described in detail in this report).

2. Testing and evaluation of the 3rd party sensors

2.1. Sensors for weight and body composition monitoring

2.1.1. Selected sensors for investigation

Based on previous investigation in Task 2.3, the following devices for weight and body composition monitoring have been preselected for investigation:

- iHealth HS5 Wi-Fi¹ (entitled as iHealth)
- Medisana BS 440 Connect²(entitled as Medisana)
- Medisana Target Scale 2³ (entitled as Targetscale)

As the list of observables has been updated and the total body water (TBW) parameter had been removed, two additional scales were included in investigation:

- Withings Smart Body Analyzer4 (entitled as Withings)
- Fitbit Aria Scale5 (entitled as Fitbit)

¹ <u>http://www.ihealthlabs.com/wireless-scales/wireless-body-analysis-scale/</u> (Last accessed: 01/21/2015)

² <u>http://www.medisana.com/en/Health-control/Personal-scales/Body-analysis-scale-with-Bluetooth-BS-440-connect.html</u> (Last accessed: 01/21/2015)

³ <u>http://www.vitadock.com/targetscale/targetscale-benefits.html</u> (Last accessed: 01/21/2015)

⁴ <u>http://www.withings.com/us/smart-body-analyzer.html</u> (Last accessed: 01/24/2015)

⁵ <u>http://www.fitbit.com/aria</u> (Last accessed: 01/24/2015)



2.1.2. Testing and evaluation methodology

The testing of the selected devices was accomplished by comparison to the reference device (see Figure 1). Three main parameters: weight (kg), Total Body Water (%) and Fat (%) were used for comparison. Professional Tanita TBF-300A Body Composition Analyzer (Tanita Corporation, Tokyo, Japan) was used for the reference measurements. Bio-impedance analysis measurements of this device are declared by manufacture to be within 5% of DEXA (Dual-energy X-ray absorptiometry), the gold standard.

There were performed 2 tests for weight (kg), fat (%) and Total Body Water (%) measurement accuracy estimation:

- Test No.1: 10 subjects (2 females), 30 measurements with each weight scale (Targetscale, Medisana, iHealth)
- Test No.2: 14 subjects (2 females), 42 measurements with each weight scale (Withings, Fitbit).

Each subject stood on the scale three times on each scale in series. Weight and fat percentage was measured. Personal information, such as the date of birth, height and sex was filled in to the user account at the beginning. Account information was synchronized with the scale prior to the measurement.

The 3^{rd} test aimed to investigate linearity of body weight change detection by the devices. One subject participated in the experiment. The subject weight was increased linearly in the range of 0 - 1 kg with small additions (0.1 kg) of liquid to the small tank held by the subject. The test was repeated 3 times.

Bland – Altman diagrams⁶ are used for visual presentation of testing results. The accuracy components (mean of differences and standard deviation) are summarized in table for numerical comparisons.



Figure 1. Body composition scales: Medisana (a, top), Withings (a, bottom), Tanita (b, top), Targetscale (b, bottom), iHealth (c, top), Fitbit (c, bottom)

⁶ Altman DG, Bland JM (1983). "Measurement in medicine: the analysis of method comparison studies". The Statistician 32: 307–317



2.1.3. Results of testing and comparison

The results of weight scales testing are presented by Bland - Altman diagrams (Figure 2 – Figure 4) and summary is presented in Table 1. In weight measurement, the lowest mean error is achieved by the Fitbit scale with error of 0.00 ± 0.12 kg. However, its SD of error is slightly higher than the Withings scale. The Withings scale overestimates weight by 0.19 ± 0.08 kg. The Medisana scale also shows good performance with error of -0.07 ± 0.17 kg.The least accurate weight scale is the Targetscale. It overestimates weight by 0.42 ± 0.15 kg. iHealth weight scale demonstrated average accuracy (0.21 ± 0.28 kg).



Figure 2. Testing results: weight

All tested body composition weight scales were able to estimate body fat percentage. The testing results in terms of Bland – Altman diagrams are presented in Figure 3. Fitbit and iHealth scales showed the best performance with error of $0.84\pm0.62\%$ and $0.75\pm0.53\%$ respectively. The mean error of Medisana scale is even lower (0.28%) but SD is much higher (2.42%) than the previous two. The worst performance was demonstrated by Targetscale (0.94±2.96%). The average performance was shown by Withings scale (1.72±1.25%).

Parameter "Total body water" was measured by only 3 out of 5 scales: Targetscale, Medisana, iHealth. Each of these scales demonstrates average performance. Targetscale and Medisana scale have low mean error (0.07% and 0.35% respectively) but high SD (1.97% and 2.19%, respectively). On the other hand, iHealth scale has lower SD (0.90%) but very high mean error (-4.00%).





Figure 3. Testing results: fat



Figure 4. Testing results: Total Body Water (TBW)

Table 1. Comparison of weight scales						
	Error in weight, kg		Error in fat, %		Error in TBW, %	
Device	Mean	SD	Mean	SD	Mean	SD
Targetscale	0.42	0.15	0.94	2.96	0.07	1.97
Medisana	-0.07	0.17	0.28	2.42	0.35	2.19
iHealth	0.21	0.28	0.75	0.53	-4.00	0.90
Fitbit	0.00	0.12	0.84	0.62	N/A	N/A
Withings	0.19	0.08	1.72	1.25	N/A	N/A



The results of the 3rd test are presented in Figure 5. It can be observed that Medisana and Withings scales were unable to detect small changes (0.1 kg) of weight in several instances. However, these errors are within the manufacturers specifications. Therefore all these devices are suitable in weight change detection.



Figure 5. Body weight change detection

2.1.4. Conclusion

Accuracy of all devices for weight measurement is acceptable. Medisana scale (price 70 EUR) provides the largest amount of observables (including Total Body Water), but its usability requires improvement. iHealth scale (price 120 EUR) has the worst performance and inadequate mechanical design. Fitbit scale (price 130 EUR) is the most accurate, but it synchronizes only via Wi-Fi network. On the other hand, the accuracy of the Withings scale (price 150 EUR) is slightly worse than Fitbit, but it also measures heart rate, which is another important observable. Withings scale synchronizes via Wi-Fi network, or via Bluetooth, if Wi-Fi is not available.

In final conclusion:

- Fitbit scale is recommended if kidney related observables (such as weight) are more important than heart related observables, and there is a Wi-Fi network available at patient's home;
- Withings scale is recommended if heart related observables (such as heart rate) are more important than kidney related observables, or there is no Wi-Fi network available at the patient's home;
- Medisana scale is recommended if hydration related observables are important.

2.2. Sensors for physical activity monitoring

2.2.1. Selected sensors for investigation

Based on previous investigation in Task 2.3, the following devices have been preselected for investigation:

- Fitbit One⁷ (entitled as One)
- Fitbit Flex⁸ (entitled as Flex)

⁷ <u>http://www.fitbit.com/one</u> (Last accessed: 01/09/2015)

⁸ <u>http://www.fitbit.com/flex</u> (Last accessed: 01/09/2015)



- iHealth Wireless Activity and Sleep Tracker⁹ (entitled as iHealth)
- Medisana VIFIT Connect¹⁰ (entitled as Vifit)
- Samsung Gear Live¹¹ (entitled as Gear)

Also, the following smartphone apps have been selected:

- Samsung S Health¹² (entitled as Shealth)
- Moves¹³ (entitled as Moves)
- Endomondo Sports Tracker¹⁴ (entitled as Endo)
- Google My Tracks¹⁵ (entitled as Tracks)

2.2.2. Testing and evaluation methodology

The testing of the selected devices was accomplished by comparison to the reference methods. Three main parameters: step count, distance traveled and energy consumption (calories burned) were used for comparison. The following testing equipment was used for the reference measurements:

- Cosmed K4b2 portable system for indirect calorimetry measurement of energy consumption (in kcal) with additionally placed GPS sensor for distance measurements (m);
- KTU BII Cardiologger v6 attached to the waist was used to acquire accelerometer signal. Later on, interactive peak detection based step counting algorithm (implemented in Matlab, Mathworks Inc.) was used for step count calculation.

One of the test subjects is presented in Figure 6 with all testing equipment on.



Figure 6. Mounting of testing equipment and sensors on the subject

- ¹⁰ <u>http://www.medisana.com/en/Sport/Activity-Tracker/ViFit-connect-Activity-Tracker-mag.html</u> (Last accessed: 01/09/2015)
- ¹¹ <u>http://www.samsung.com/global/microsite/gear/gearlive_design.html</u> (Last accessed: 01/09/2015)
- ¹² <u>http://content.samsung.com/us/contents/aboutn/sHealthIntro.do</u> (Last accessed: 01/09/2015)
- ¹³ <u>https://www.moves-app.com/</u> (Last accessed: 01/09/2015)
- ¹⁴ https://www.endomondo.com/ (Last accessed: 01/09/2015)
- ¹⁵ <u>https://play.google.com/store/apps/details?id=com.google.android.maps.mytracks</u> (Last accessed: 01/09/2015)

⁹ <u>http://www.ihealthlabs.com/fitness-devices/wireless-activity-and-sleep-tracker/</u> (Last accessed: 01/09/2015)



The overall testing comprised of two main parts:

- Controlled environment test a short test at the beginning of each experiment comprising of two simple walking and running exercises at the fixed distance and pace. The purpose of this test was to estimate the average step length while walking and running, therefore only accelerometer device was used as a reference. Some of the commercial devices required such step length data (see Table 2.) in order to track distance more accurately. It was also useful to determine the behavior of the devices in relatively short physical activity episodes. This test was accomplished in the hall of the KTU Santaka Valley building, which is 80 m long (see Figure 7). After this test, all required data was calculated and synchronized with the devices.
- Uncontrolled environment test the main test where the participant was able to choose his own walking
 pace and some parts of the route. All equipment, described earlier, was used. Data was recorded after
 each part. This test was divided into 4 parts:
 - 1000 m long casual walking exercise where the participant was able to choose his own walking pace. The default route for the exercise was predefined (see Figure 7). It was designed to represent common walking activities in daily life.
 - 200 m long running exercise short exercise of running 100 m forward and back without stopping, at a slow pace (close to jogging). This was carried out in order to find out how well each device works under running conditions.
 - 200 m long slow walking exercise walking 100 m forward and back without stopping, at a very slow pace. This was carried out in order to find out how well each device works under non-standard walking conditions.
 - 5 floors stair climbing exercise was carried out mainly in order to find out how well energy estimation works in each device. There can be no distance estimation comparison, because the GPS sensor does not work inside the building.



Figure 7. Controlled environment testing site (left) and the uncontrolled environment testing track (right)



Table 2. Personal data required before the test						
Device	Birth date	Height	Weight	Step length	Running step length	
Flex	✓	✓	✓	~	✓	
One	✓	✓	✓	~	✓	
iHealth	✓	✓	✓	_	_	
Vifit	_	✓	✓	~	_	
Gear	—	_	_	—	—	
Shealth	—	✓	✓	—	—	
Moves	—	-	_	—	-	
Tracks	_	_	\checkmark	_	_	
Endo	✓	✓	✓	_	_	

The whole protocol can be described briefly:

- 1. Controlled environment 160 walking test (80 m forward and back with pause).
- 2. Controlled environment 160 running test (80 m forward and back with pause).
- 3. Uncontrolled environment 1000 m walking test (round track, no pause).
- 4. Uncontrolled environment 200 m running test (100 m forward and back, no pause).
- 5. Uncontrolled environment 200 m slow walking test (100 m forward and back, no pause).
- 6. Uncontrolled environment 5 floors climbing test (5 floors up and down, pause on the top).

Overall, 4 subjects participated in the experiments: 3 males and 1 female. The results were processed calculating relative error for each measurement. In order to summarize the results, the mean value and the standard deviation of the relative errors were calculated. However, due to the small number of participants, we decided to additionally use the non-parametric Mann-Whitney U test¹⁶ statistic method. It is the null hypothesis test, where the null hypothesis is that datasets from a tested device and the reference are the same. The p value shows probability of the null hypothesis.

The results were divided in two categories:

- simple walking activities (including 1st, 3rd and 5th exercises);
- less frequent activities (including 2nd, 4th and 6th exercises).

In order to rank the physical activity devices and mobile apps, the following criteria were used:

- 1. The mean error is the most significant.
- 2. The SD of error is less significant than the accuracy.
- 3. The p value from the non-parametric test is the least significant.
- 4. Overall, the first category (simple walking activities) is more important than the second one (less frequent activities).

If the performance of the device (or the mobile app) is selected as the best in two or more criteria, the device is considered superior.

¹⁶ Mann-Whitney U test. Online: <u>http://en.wikipedia.org/wiki/Mann%E2%80%93Whitney_U_test</u> (Last accessed: 01/09/2015)



2.2.3. Results of testing and comparison

Summarized results from the physical activity sensors testing are presented in the tables bellow. Table 3 – Table 5 fall into the first category (simple walking activities) and Table 6 – Table 8 fall into the second category (less frequent activities). Bold values depict the best result in each line. These best results were chosen individually for both – devices and apps.

	Table 3. Results from controlled environment 160 m walking test.								
	Devices Apps					ops			
Flex One iHealth Vifit			Vifit	Gear	Shealth	Moves			
Error in	Mean	15,3%	1,0%	5,5%	48,5%	22,8%	2,6%	17,4%	
steps	SD	16,8%	0,6%	7,3%	34,1%	32,4%	2,1%	12,0%	
p va	lue	0,206	0,802	0,397	0,206	0,206	0,857	0,198	

Table 4. Results from uncontrolled environment 1000 m walking test.										
		Devices					Apps			
		Flex	One	iHealth	Vifit	Gear	Shealth	Moves	Tracks	Endo
Error in	Mean	-12,7%	-0,8%	-5,7%	-16,0%	-2,0%	-0,5%	-0,4%	N/A	N/A
steps	SD	11,2%	1,1%	4,8%	6,5%	3,9%	1,6%	9,1%	N/A	N/A
p val	ue	0,056	0,579	0,222	0,032	0,548	0,310	0,548	N/A	N/A
Error in	Mean	-17,3%	-5,8%	-48,1%	-20,1%	N/A	10,0%	N/A	1,5%	0,5%
distance	SD	6,8%	4,5%	2,4%	4,2%	N/A	21,5%	N/A	3,2%	0,8%
p val	ue	0,008	0,016	0,008	0,008	N/A	0,841	N/A	0,333	0,516
Error in	Mean	27,4%	24,2%	36,2%	-38,6%	N/A	-8,3%	N/A	7,0%	-9,3%
energy	SD	41,9%	17,2%	17,7%	10,3%	N/A	14,3%	N/A	30,8%	10,9%
p val	ue	0,151	0,056	0,008	0,008	N/A	0,151	N/A	0,690	0,802

Table 5. Results from uncontrolled environment 200 m slow walking test.								
				Devices			Apps	
		Flex	One	iHealth	Vifit	Gear	Shealth	Moves
Error in stone	Mean	-17,4%	-7,4%	-17,5%	-24,0%	-1,2%	1,1%	-26,1%
Error in steps	SD	21,2%	6,5%	19,8%	15,8%	8,7%	10,5%	26,5%
p value		0,200	0,486	0,486	0,114	0,886	1,000	0,114
Error in distance	Mean	-3,4%	13,6%	-39,9%	-9,4%	N/A	11,0%	N/A
Enor in distance	SD	12,5%	16,4%	19,2%	15,3%	N/A	36,6%	N/A
p value		1,000	0,143	0,029	0,343	N/A	1,000	N/A
	Mean	65,6%	55,6%	61,4%	-34,7%	N/A	-20,1%	N/A
Endrinenergy	SD	20,9%	26,2%	36,8%	14,7%	N/A	15,8%	N/A
p value		0,029	0,029	0,114	0,086	N/A	0,343	N/A

The Fitbit One is superior sensor among the physical devices in the simple walking activities category. It shows the best performance for all observables in controlled environment walking test, as well as in the uncontrolled environment test; it shows however a slightly lower performance (although not the worst) in slow walking test. On the contrary, there is no clear winner on the mobile apps side. Endomondo sports tracker showed the best



performance in long walking test, while Samsung S Health showed the best performance in short tests. Moves showed the best performance in counting steps during the long walk experiment. On the other hand, Samsung S Health is platform dependent (Samsung S4 and S5 only), while Moves does not output energy expenditure and Endomondo Sport Tracker use only GPS (which is not suitable for indoor monitoring).

Table 6. Results from controlled environment 160 m running test.								
Devices Ap					ps			
		Flex	One	iHealth	Vifit	Gear	Shealth	Moves
Error in	Mean	-15,8%	-14,6%	-7,7%	-16,9%	-2,7%	0,4%	-76,5%
steps	SD	9,1%	5,9%	12,6%	19,2%	2,2%	10,0%	29,2%
p value		0,029	0,029	0,457	0,257	0,629	1,000	0,029

Table 7. Results from uncontrolled environment 200 m running test.								
				Devices			Apps	
		Flex	One	iHealth	Vifit	Gear	Shealth	Moves
Error in stone	Mean	-15,6%	-11,2%	-10,9%	-16,3%	-1,8%	18,7%	-84,4%
Error in steps	SD	14,6%	7,0%	11,7%	17,2%	2,1%	37,5%	4,6%
p value		0,086	0,229	0,143	0,343	0,857	0,486	1,000
Error in distance	Mean	-44,9%	-26,9%	-56,8%	-45,8%	N/A	8,0%	N/A
Endi in distance	SD	5,0%	26,3%	22,9%	16,9%	N/A	20,0%	N/A
p value		0,029	0,314	0,029	0,029	N/A	1,000	N/A
	Mean	59,4%	61,7%	66,2%	-31,5%	N/A	58,0%	N/A
Enor in energy	SD	4,8%	18,9%	21,7%	15,4%	N/A	15,7%	N/A
p value		0,029	0,029	0,029	0,057	N/A	0,029	N/A

Table 8. Results from uncontrolled environment stairs climbing test.								
				Devices			Ap	ps
		Flex	One	iHealth	Vifit	Gear	Shealth	Moves
Error in stops	Mean	-6,9%	0,7%	-1,3%	-19,4%	0,6%	6,2%	-22,9%
Error in steps	SD	11,2%	5,1%	9,0%	11,2%	7,0%	9,0%	13,6%
p value		0,343	0,457	0,371	0,057	0,486	0,886	0,029
	Mean	26,4%	27,2%	17,3%	-51,5%	N/A	-31,8%	N/A
Enor in energy	SD	16,4%	20,3%	11,4%	3,2%	N/A	16,1%	N/A
p value	!	0,057	0,086	0,057	0,029	N/A	0,029	N/A

Results from the less frequent activities testing experiments are inconclusive. Each device is superior in different test for the different observables. Such outcome should be expected as these devices probably are designed to be used in simple walking activities, which occur most of the time in one's daily life. On the mobile apps side, the Samsung S Health seems to perform better than the Moves app, but the problems stated earlier arise as well.

2.2.4. Conclusion

Fitbit One is clearly superior device for the physical activity monitoring in simple walking activities. While there is no other such device in the other category, the Fitbit One is proposed as the most appropriate device. Its



splash- and sweat-proof case, clear design, user-friendly mobile app and relatively low price only confirm this proposal. On the other hand, high error rates of energy estimation and limitations due to less frequent activities should be kept in mind.

We should also conclude that there is no superior app for the physical activity monitoring. While each app shows some advantages under specific conditions, their disadvantages are more important. The most important disadvantage is clear – mobile phone should be always carried by the person in order for the app to work precisely.

2.3. Sensors for blood glucose measurement

2.3.1. Usability and functionality investigation

Two personal glucometer devices were acquired for investigation: iHealth BG5¹⁷, Medisana Meditouch 2¹⁸. Since we did not have any possibility to test the accuracy of these devices, this chapter includes only the usability and functionality investigation.

iHealth glucometer is wireless and synchronizes via iHealth Gluco-Smart¹⁹ app. However, this app is unavailable in Europe at the moment. The device itself has on-board display which is very bright and not comfortable. The iHealth glucometer is quite expensive (price about 70 EUR) and works only with original iHealth strips.

The Medisana glucometer needs an USB connection and personal computer (PC) software in order to synchronize the data from the device to the cloud. However, the device has a 480 memory slots that enable to perform this synchronization only once in a while. Meditouch 2 has large and clear display, is relatively cheap (about 22 EUR) and seems to work with any kind of test strips.

2.3.2. Conclusion

The fact that iHealth Gluco-Smart app seems to be unavailable in Europe rules out the possibility to choose this device. Furthermore, the only disadvantage of Medisana Meditouch 2 against iHealth glucometer is the wired connection and PC software, but the on-board memory softens this problem. In overall, we propose to use Medisana Meditouch 2 glucometer for blood glucose monitoring.

2.4. Sensors for cardiovascular state monitoring

2.4.1. Selected sensors for investigation

Based on previous investigation in Task 2.3, the following devices for blood pressure monitoring have been preselected for investigation:

- Medisana BU575 Connect²⁰ (entitled as Medisana)
- iHealth BP5²¹ (entitled as iHealth)

¹⁷ <u>http://www.ihealthlabs.com/glucometer</u> (Last accessed: 01/21/2015)

¹⁸ <u>http://www.medisana.com/en/Health-control/Blood-glucose-monitor/MediTouch-2-mg-dL-Blood-glucose-monitor-incl-starter-set.html</u> (Last accessed: 01/21/2015)

¹⁹ <u>https://play.google.com/store/apps/details?id=jiuan.androidBg.start</u>

²⁰ <u>http://www.medisana.com/en/Health-control/Blood-pressure-monitor/Upper-arm-blood-pressure-monitor-with-Bluetooth-BU-575-connect.html</u> (Last accessed: 01/21/2015)

²¹ <u>http://www.ihealthlabs.com/blood-pressure-monitors/wireless-blood-pressure-monitor/</u> (Last accessed: 01/21/2015)



Withings Blood Pressure Monitor²² (entitled as Withings)

Also, eMotion Faros 180°²³ ECG recording device have been selected for the simple testing, since there is no suitable investigation methodology and this device has no worthy competitors.

2.4.2. Testing and evaluation methodology

All providers of selected ambulatory blood pressure devices declare the same pressure measurement accuracy ± 3 mm Hg^{24,25,26} which seems suitable for ambulatory monitoring. However, resent debates raised some concerns about the accuracy of new "smart" (smartphones and App based) blood pressure monitors²⁷. Thus we decided to test the selected devices.

There are 3 recognized protocols specifically designed for validation of blood pressure devices: 1) the British Hypertension Society (BHS) protocol²⁸, 2) the Association for the Advancement of Medical Instrumentation / International Standards Organization (AAMI/ISO) protocol²⁹, 3) the International Protocol published by the European Society of Hypertension (ESH)³⁰. For example, AAMI standard says that the mean difference between different blood pressure measurement methods must be less than ±5 mmHg and the SD (standard deviation) must be less than ±8 mmHg with 85% of the measurements in the 20-250 mmHg range. Accuracy better than ±10 mmHg must be achieved with 95% of the measurements. All three standards require to perform validation of blood pressure measurement devices on human subjects against auscultatory method (standard mercury sphygmomanometer) with 2 human observers. ESH protocol requires 33 subjects, other two standards – 85 subjects. Due to many restrictions on subjects' population composition: age, gender, arm circumference etc. these device validation studies are complex, time consuming and expensive.

Less time consuming and cheaper BP monitoring device testing method is based on application of specialized patient simulators (Figure 8 (a), (b)). Patient simulators are devices used for testing and calibration of clinical patient monitors and they are able to simulate various vital signs: electrocardiogram, non-invasive blood pressure, invasive blood pressure, oxygen saturation, patient respiration, patient temperature etc. Both patient simulators (shown in Figure 8 (a), (b)) are able to simulate human blood pressure changes for both systolic and diastolic measures induced oscillometric vibrations in the whole dynamic range 20 -240 mmHg. The simulators are embedded in pneumatic circuit between BP monitor and cuff.

²⁵ Medisana BU 575 connect, Manual, <u>http://www.medisana.com/out/pictures/media/manual/51296bu575connectwestv1</u> <u>4webam20140303.pdf</u> (Last accessed: 01/21/2015)

²² <u>http://www.withings.com/us/blood-pressure-monitor.html</u> (Last accessed: 01/21/2015)

²³ <u>http://www.megaemg.com/products/faros/</u> (Last accessed: 01/21/2015)

²⁴ iHealth BP5 Technical Specs, <u>http://www.ihealthlabs.com/blood-pressure-monitors/wireless-blood-pressure-monitor/</u> (Last accessed: 01/21/2015)

²⁶ Withings blood pressure monitor Tech specs, <u>http://www.withings.com/us/blood-pressure-monitor-tech.html</u> (Last accessed: 01/21/2015)

²⁷ Inaccuracy plagues mobile blood pressure devices <u>http://www.ehospitalistnews.com/index.php?id=2050&type=98&tx</u> <u>ttnews[tt_news]=286065&cHash=da03e20e36</u> (Last accessed: 01/21/2015)

²⁸ O'Brien E, Petrie J, Littler WA, et al. The British Hypertension Society Protocol for the evaluation of blood pressure measuring devices. J Hypertens. 1993;11 Suppl 2:S43–S62.

²⁹ Association for the Advancement of Medical Instrumentation. American National Standard: non-invasive sphygmomanometers – part 2: clinical validation of automated measurement type; ANSI/AAMI/ISO. 2009;81060– 81062.

³⁰ O'Brien E, Atkins N, Stergiou G, et al. Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol Revision 2010 for the validation of blood pressure measuring devices in adults. Blood Press Monit. 2010;15:23–38.





Figure 8 AccuSim-BP Handheld NIBP Simulator (a), Fluke Prosim 8 (b), and measurement setup (c)

Patient simulators have advantages and disadvantages against living subjects based validation of BP measuring devices. One important advantage e of this method is possibility to perform comparison of different BP monitors in equal conditions and to minimize influence of various physiological effects. It is known that systolic and diastolic blood pressure values of a person are varying. These variations are due to different origins including respiration which causes 3–6 mmHg variation in the SBP while in normal respiration and 15–20 mmHg when breathing heavily³¹. Because oscillometric measurement methods determine the instantaneous SBP/DBP values, this results in a low reproducibility. In addition, the patient simulator method minimizes comparison subjectivity. Aforementioned reasons motivated to employ specialized BP patient simulator "AccuSim-BP Handheld NIBP Simulator" (Datrend Systems Inc., Canada) for comparisons of 3 selected "smart" BP monitors. Two popular automatic ("classical") BP monitors were included into the study as well.

2.4.3. Results of testing and comparison

We tested 3 "smart" and 2 "classical" devices. Accuracy and precision in terms of mean difference and SD of tested blood pressure sensors are presented in Table 9. It can be observed that all devices fulfill accuracy requirements of BPM validation protocols (mean difference <10 mmHg). The negative signs in front of mean differences point out to underestimation of BP measurements.

Table 9. Testing results of smart blood pressure monitors with AccuSim-BP NIBP simulator						
Device	Error in Systol	ic BP, mmHg	Diastolic BP, mmHg			
Device	Mean	SD	Mean	SD		
Medisana	-1.1	2.8	-0.1	1.2		
iHealth	-6.6	2.7	1.9	1.5		
Withings	-4.9	1.6	N/A	N/A		
LogicoDigit	1.0	4.0	6.0	4.0		
Microlife	4.0	1.9	5.0	2.5		

Due to technical problems testing of diastolic BP in Withings BPM case was unsuccessful. Therefore we rely on independent validation results³², which show that mean difference is 0.4 mmHg and SD is \pm 4.2 mmHg in diastolic BP measurements.

³¹ M. Ramsey, III, "Blood pressure monitoring: Automated oscillometric devices" J. Clin. Monit. Comput., vol. 7, no. 1, pp. 56–67, Jan. 1991.

³² Topouchian J, Agnoletti D, Blacher J, Youssef A, Chahine MN, Ibanez I, Assemani N, Asmar R. Validation of four devices: Omron M6 Comfort, Omron HEM-7420, Withings BP-800, and Polygreen KP-7670 for home blood pressure measurement according to the European Society of Hypertension International Protocol. Vasc Health Risk Manag. 2014 Jan 16;10:33-44.



Figure 9 and Figure 10 show graphical representation of testing results for SBP and DBP values in terms of XY diagrams (measured parameter against the reference) and Bland – Altman plots (the difference against the average of measured and reference values).



Figure 9 Testing results for SBP values: XY diagram (a), Bland - Altman diagram (b)



Figure 10. Testing results for DBP values: XY diagram (a), Bland - Altman diagram (b)

2.4.4. Conclusion

Medisana blood pressure monitor (BPM) has a number of advantages:

- it is the most accurate;
- it measures blood pressure while inflating the cuff, therefore the discomfort is lower and the measurement is shorter;
- has on board display;
- powered by rechargeable battery, which lasts for a few months;
- has memory of up to 180 measurements;



- also works as an alarm clock, therefore promotes to keep it on a nightstand and measure daily blood pressure in the morning, as the alarm goes off;
- it is relatively cheap (about 100 Euro).

However, there are two main disadvantages:

- it does not allow to enter data manually;
- the synchronization is slow (about 1 min. 30s, while the measurement itself only 30s) and does not work 100% of the time.

We propose that problems with Medisana synchronization could be alleviated by using its internal memory. If some problems occur, the synchronization phase could be skipped for that day and resumed manually the next day.

On the other hand, Withings blood pressure monitor is operated more easily, the app and synchronization works all the time. However, it has no rechargeable batteries, no memory, no display, the accuracy is lower and the price is higher (130 EUR), than Medisana BPM.

iHealth BPM is similar to the Withings BPM in terms of functionality and control with the advantage of measuring blood pressure while inflating the cuff (shorter and more comfortable measurement process). However, it is the least accurate among tested devices.

Therefore, Medisana BU-440 is preferred BPM since it has the number of operating related advantages and is the most accurate. If the ease of operation is especially important, Withings BPM could be chosen.

3. Investigation of possibilities to develop new sensors and algorithms

The results from testing and evaluation of 3rd party sensors showed that they are not perfectly suitable for the project. While some of them lack for functionality, some lack for the ease of use, others lack for both. We see a need for the three custom hardware and software modules development. The first proposed hardware module is wristwatch type device suitable for long-term usage, which could integrate sleep apnea and some of the cardiovascular parameters monitoring. The second proposed hardware module is weight scale system for intermittent monitoring of weight, hydration and cardiovascular parameters. The last one is a software module with an algorithm for atrial fibrillation detection from ECG signals. The concepts of these three modules are presented in more detail in the following chapters.

3.1. Wristwatch for continuous health parameters monitoring

3.1.1. Motivation

Wristwatch is the longest known wearable device. It is considered completely unobtrusive and could be accepted by patients for continuous monitoring. Existing commercial smart wristwatches already try to measure some health related parameters (heart rate, steps, or burned calories). However, we anticipate that more specific observables e.g. arrhythmias (ventricular premature beats, atrial fibrillation), pulse rate variability, or sleep apnea parameters could be also monitored. These information channels could open new windows to the cardiorenal syndrome patient health condition. The list of observables, which could be monitored using some specific wristwatch type device is presented in Table 10.



Table 10. Personal data required before the test					
Observable	Method				
Apnea – hypopnea index (AHI)	SpO2, PPG-derived breathing, inertial measurements				
Heart rate	PPG				
Breathing rate	PPG				
Metabolic equivalent (MET)	PPG, GSR, inertial measurements				
Physical exercise	PPG, GSR, inertial measurements				
Premature ventricular contraction (PVC)	PPG				
Atrial fibrillation (AF)	PPG				

As already mentioned, physical activity related parameters (energy consumption – MET, physical exercise) and heart rate are monitored by already commercially available smartwatches. Even though they may not be very accurate at the moment, there are interesting future plans from big and experienced companies. Some new greatly improved trackers are already available on the market e.g. Fitbit Surge³³, Jawbone UP3³⁴. We expect that sooner or later these new generation physical activity trackers will solve most of the previous tracker problems. Therefore, we do not propose to include the monitoring of these lifestyle related observables in the new sensor development.

On the other hand, the monitoring of such health related observables as AHI and arrhythmias are not that welldeveloped for independent home care applications. There are only few cases known for arrhythmia³⁵ (e.g. PVC³⁶, AF³⁷) detection in simple and unobtrusive way. While some systems are commercially available for sleep apnea monitoring at home (Pacific Medico Sleep diagnostic device³⁸, Braebon Medibyte³⁹), they could be hardly identified as unobtrusive. Therefore, we propose to conduct/continue the research in these two fields in order to develop new sensors. However, it is crucial to understand that these proposed problems are entirely a matter of the scientific research with no assured results or solutions. There is a possibility to provide such sensors for some of the subjects in the pilot phase, but definitely not for all of them.

3.1.2. The concept of implementation

The main idea of CARRE wristwatch is to improve personal data observables monitoring in 3 ways:

- to provide higher quality data (raw signals) for signal processing units;
- to address several kinds of observables with one device (multi-parametric sensing);
- to improve convenience (e.g. comparing to Holter monitors).

The technical and functional specification of CARRE wristwatch and explanation is presented in Table 11. It must be noted that unobtrusiveness and convenience is one of the most important factors.

³³ <u>https://www.fitbit.com/surge</u>

³⁴ <u>http://jawbone.com/store/buy/up3</u>

³⁵ T. Suzuki, K. I. Kameyama, and T. Tamura, "Development of the irregular pulse detection method in daily life using wearable photoplethysmographic sensor", 31st Ann. Int. Conf. IEEE EMBS, pp. 6080–6083, 2009.

³⁶ E. Gil, P. Laguna, S. Member, and J. P. Mart, "Heart Rate Turbulence Analysis Based on", IEEE Trans. Biomed. Eng., vol. 60, no. 11, pp. 3149–3155, 2013.

³⁷ J. Lee and B. Reyes, "Atrial fibrillation detection using an Iphone 4S", IEEE Trans. Biomed. Eng., vol. 60, no. 1, pp. 203–206, 2013.

³⁸ Pacific Medico Co. Ltd., Respiratory Care Product <u>http://www.pacific-medico.com/english/division_2.html</u>

³⁹ Braebon – Medibyte http://www.braebon.com/products/medibyte/



Table 11. Wristwatch technical and functional requirements				
Requirement	Details			
Green LED PPG channel	As our previous research shows ⁴⁰ , it is highly suitable for PPG in the wrist area. This PPG signal should be used for AF and PVC detection.			
Red LED PPG channel	Suitable for SpO2 measurement			
IR LED PPG channel	Suitable for SpO2 measurement.			
3-axis accelerometer				
3-axis gyroscope	Suitable for inertial measurements.			
Altimeter				
At least 24 hours operating time	-			
Wireless communication for control	For minimum unobtrusiveness. Bluetooth protocol preferred due to smartphone compatibility.			
Micro SD memory card for primary stage	Minimum 4 GB.			
SpO2 measurement	-			
Real-time PVC detection				
Real-time AF detection	Possible research output. Based on algorithms developed by KTU.			
Sleep apnea detection				
Minimalistic user interface	For maximum upohtruciveness and user-friendly maintenance			
High comfort				

General concept of the device is presented in Figure 11. It can be divided into three layers. The hardware is the most simple one and the implementation should be relatively easy. In measurements layer, there are some risks and uncertainties:

- PPG waveform often suffer from movement artifacts, which disturb further measurements;
- the accuracy of SpO2 value might depend on different LED characteristics, temperature, etc.;
- there is no clear approach of quantitative measurements of the movement.

The algorithmic layer seems to be the most challenging. The development of algorithms heavily depends on available data from clinical studies, physiological information input, and ability to test under realistic conditions.

⁴⁰ V. Vizbara, A. Sološenko, D. Stankevičius, and V. Marozas, "Comparison of green, blue and infrared light in wrist and forehead photoplethysmography", in Biomedical Engineering 2014, 2013, pp. 78–81.





Figure 11. Structure of the CARRE wristwatch system

CARRE wristwatch integration into CARRE scheme could not be specifically described yet. It should be implemented under some "Custom API", or via "CARRE consortium cloud". The latter ones will be described in Chapter 4 of this document.

It should be understood that this is only a primary concept of the CARRE wristwatch. It will definitely be deepened and expanded in future, as our understanding of the problem increases.

3.2. An algorithm and software module for arrhythmia detection

3.2.1. Motivation

Atrial fibrillation (AF) is one of the most common cardiovascular conditions encountered in clinical practice. AF is a progressive arrhythmia associated with detrimental effects on human hemodynamics, increased risk of stroke and heart failure⁴¹. Various studies show that renal diseases and AF frequently coexist and complicate treatment of both conditions^{42,43,44}.

In today's clinical practice, a qualitative approach for confirmation of AF presence (yes or no AF) is preferred which usually relies on analysis of ECG recorded during rest or 24-hour Holter monitoring. While standard techniques are suitable for reliable detection of permanent or persistent AF, nevertheless, they are associated with high chances of missing paroxysmal AF episodes that usually appear at the beginning of arrhythmia development⁴⁵. In order to detect paroxysmal AF episodes, novel patient-friendly diagnostic utilities for long-

⁴¹ Ball J, Carrington MJ, McMurray JJ, Stewart S. Atrial Fibrillation: Profile and Burden of an Evolving Epidemic in the 21st Century. *Int J Cardiol*, 167; 2013:1807-24.

⁴² Reinecke H, Brand E, Mesters R. Dilemmas in the management of atrial fibrillation in chronic kidney disease. *J Am Soc Nephrol.* 20; 2009:705-11.

⁴³ Piccini JP, Stevens SR, Chang Y., et al. Renal dysfunction as a predictor of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. *Circulation*, 127; 2013:224–32.

⁴⁴ Wong CX, Lau DH, Sanders P. Atrial fibrillation epidemic and hospitalizations: how to turn the rising tide? *Circulation* 129; 2014:2361–3.

⁴⁵ Charitos EI, Stierle U, Ziegler PD, et al. A comprehensive evaluation of rhythm monitoring strategies for the detection of atrial fibrillation recurrence: insights from 647 continuously monitored patients and implications for monitoring after therapeutic interventions. *Circulation* 126; 2012:806 – 14.



term ambulatory ECG monitoring have been proposed⁴⁶. Moreover, extended AF monitoring enables the possibility of changing the prevailing concept of qualitative AF assessment to quantitative (the amount of AF) approach.

Standard time domain parameters applied for heart rate variability analysis, i.e. standard deviation of RR intervals or root mean square differences of successive intervals can be used for AF analysis as well. However, more specific parameters, such as AF burden and AF density, are preferred for quantitative evaluation of paroxysmal AF⁴⁵. AF burden is expressed as a proportion of time a patient is in AF, and therefore does not provide information about temporal AF behavior. The purpose of AF density is to evaluate temporal distribution of paroxysmal AF episodes which can be useful for assessing AF recurrence patters, i.e. relating occurring AF episodes to arrhythmia provoking events. Temporal AF pattern of AF recurrence may be of interest for drugs management and evaluation of thromboembolism risk. Furthermore, such information can be beneficial for understanding the specific factors resulting in evolving AF burden and AF density for cardio-renal patients.

3.2.2. Implementation concept

We propose a simple and low cost solution for paroxysmal AF arrhythmia detection and parametrization (Figure 12). It includes a commercial low cost single lead ECG recorder eMotion Faros 180 (Mega Electronics, Finland) and software module with the state-of-the-art algorithm⁴⁷. The algorithm was extensively tested on internationally accepted AF databases of annotated ECG signals and outperformed existing AF detectors in terms of detection accuracy and complexity. The ECG recorder is user friendly: weights 13 g, battery lasts for 3 days. The ECG signal is recorded to open source EDF file format⁴⁸.



Figure 12. Implementation concept of PAF arrhythmia detection and parametrization

The first prototype implementation of signal processing algorithms and GUI (Figure 13) is in Matlab (Mathworks Inc., Natick, USA). This implementation serves very well for testing purposes. Open source software programing language (e.g. Python) will be used for implementation of the signal processing algorithms and GUI in the next version of software module.

⁴⁶ Turakhia MP, Hoang DD, Zimetbaum P, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. Am J Cardiol 112; 2013:520–4.

⁴⁷ Petrenas A, Marozas V, Sornmo L. Low-Complexity Detection of Atrial Fibrillation in Continuous Long-Term Monitoring. Computers in Biology and Medicine, accepted for publication in "Special issue on quantitative analysis of cardiac arrhythmias", DOI: 10.1016/j.compbiomed.2015.01.019

⁴⁸ European Data Format specifications, http://www.edfplus.info/specs/edf.html





Figure 13. A prototype of GUI for PAF arrhythmia detection and parametrization

With the presented GUI, three parameters that describe paroxysmal AF are provided: the total number of paroxysmal AF episodes, AF burden and AF density. Both AF burden and AF density take values between 0 and 1. In case of AF burden, 0 indicates that no AF is observed, whereas 1 denotes that the patient was in AF throughout the entire monitoring period. In case of AF density, values close to 0 indicate that AF is uniformly spread during monitoring period, whereas values close to 1 stand for a high aggregation of AF episodes. The AF density equal to 1 is obtained when a single AF episode is observed (independently of AF episode length).

3.3. Weight scales for intermittent monitoring of body hydration and cardiovascular parameters

3.3.1. Motivation

The investigation of 3rd party body composition scales showed, that none of them are particularly well suited for project tasks. While errors in the measurement of weight and fat are acceptable, the errors in the measurement of TBW are not acceptable. Furthermore, we propose that other observables, related to cardiovascular system (such as heart rate, arrhythmia detection, intracellular and extracellular body water, pulse arrival time (PAT)⁴⁹) could be monitored via body scale, too. We can already see an example of such extended weight scale monitoring system – Withings are capable of monitoring heart rate. However, there is still a lot of room for improvement in all these commercial products.

After the analysis of scientific literature, we noticed that there are three methods available for body composition monitoring. Most of the customer grade bioimpedance measurement devices use traditional bioelectrical impedance analysis (BIA) method, which is accurate enough for assessment of healthy individuals, but is inadequate for body composition estimation in unhealthy conditions. More sophisticated methods, such as bioelectrical impedance spectroscopy (BIS) or bioelectrical impedance vector analysis (BIVA) would be more suitable for body composition monitoring in sick individuals. However, the latter two methods are not employed

⁴⁹ Paliakaitė B., Daukantas S., Sakalauskas A., Marozas V. Estimation of Pulse Arrival Time Using Impedance Plethysmogram from Body Composition Scales, accepted for publication in "IEEE Sensors Applications Symposium", 2015.



by low-cost commercial devices. On the other hand, these different methods are not so different on the hardware level. Additionally, an integrated circuit for body composition and weight measurement is available on the market which greatly simplifies the design of such bathroom scale system. Further on, the accuracy of measurements depends mostly on the algorithms and calibration data.

Overall, we propose to conduct/continue the research in this field in order to develop custom bathroom scale system. However, alike the already proposed wristwatch for continuous health parameter monitoring, the proposed problems are entirely a matter of the scientific research with no assured results or solutions. There is a possibility to provide such sensors for some of the subjects in the pilot phase, but definitely not for all of them.

3.3.2. The concept of implementation

The Figure 14 represents the concept of the weight scale monitoring system. We chose to use the case of Omron BF508 weight scale⁵⁰ as it consists of two parts with 8 electrodes in total – feet plate and handlebar. Two key components are Texas Instruments integrated circuits ADS1294 and AFE4300. The AFE4300 which was already mentioned in the above paragraph, was released by Texas Instruments in mid-2012. It contains complete analog and digital frontend for body composition scales and weight measurement. An improved version with several bug fixes was released in July of 2013. It allows to employ the BIS and BIVA methods for body composition monitoring and simplifies the overall design of the weight scale system. It is also compatible with other sensors, e.g. electrocardiography and respiration rate measurement subsystems. Therefore, we find this integrated circuit as well suited for high end scale measurement system for the project needs. The ADS1294 is dedicated for obtaining 3 channel (Einthoven leads) ECG, including right leg drive circuitry. This hardware would allow performing weight and body composition as well as ECG measurements. Further on, on integrated algorithmic level, some specific observables, e.g. heart rate or respiration rate could be calculated.



Figure 14. Structure of innovative weight scales for hydration and cardiovascular parameters monitoring

⁵⁰ <u>http://www.omron-healthcare.com/eu/en/our-products/weight-management/bf508</u> (Last accessed 2015-01-27)



Raw data could be stored on micro-SD memory card. LCD is required for instant feedback for the patient. In addition to measurement process, device should have Wi-Fi transceiver to send data to the data server. With Bluetooth (v4.0+) it would be possible to retransmit data to the server from other pre-configured devices (such as the wristwatch for continuous monitoring) without any patient intervention. It would greatly improve the ease of use of such systems and simplify the routine for the patients.

Again, alike the wristwatch for the continuous monitoring, it should be understood that this is only primary concept of the CARRE weight scale and body composition system. It will definitely be deepened and expanded in future, as our understanding of the problem increases.

4. Personal sensor data aggregator architecture and implementation

4.1. Personal sensor data aggregator concept

Means of sending data to the servers:

• Bluetooth (via Smartphone)

Wi-Fi (via Wi-Fi Router)USB (via PC software)

The idea behind the personal sensor data aggregator is to collect personal sensor data from a variety of sources, such as sensor manufacturers or health data platforms, to convert those data, regardless of origin, into RDF in accordance with the schema presented in D.2.4, and to store that RDF in the CARRE semantic repository.

The aggregator needs to be easily extensible in order to support the wide range of different data providers available, and to accommodate new providers, where necessary, as they appear.

Figure 15 presents a concept of CARRE personal sensor data aggregator. The concept shows which sensor data clouds that were preselected in D.2.3 are connected to CARRE sensor data aggregator. In order to show the system scalability and to account for future developments, the concept also presents what and how other potential sensor data sources could be integrated into CARRE system. These optional connections are shown by using dashed lines. They also show that some sensor data sources can be accessed indirectly via intermediate sensor data aggregators such as HealthVault by Microsoft Inc., Google Fit by Google Inc. or Health Kit by Apple Inc.



Figure 15. Personal sensor data aggregation concept

FP7-ICT-61140

Optional

(scalable)

Implemented



4.2. Personal sensor data aggregator design

4.2.1. Overall architecture

The personal sensor data aggregator is designed to allow easy extension with support for other devices as needed. The architecture is as shown in Figure 16.



Figure 16. Personal sensor data aggregator architecture.

4.2.2. Responder design and execution flow

Almost all of the sensor providers we support implement a "notification" or "subscription" mechanism to allow any new sensor data be sent to user-approved third-party applications whenever such data is synced with the manufacturer. These all operate in a similar way: when configuring a third-party application, the URL is specified. When new data arrives for a user who has approved that application, an HTTP GET or POST request is sent to that URL with some means of identifying the user, and the timespan covered by the new data. The application can then sync with the sensor provider servers to retrieve and store the new data.

The CARRE personal sensor data aggregator plays the role of such third-party application for each of the sensor providers we cover. The responder identified in the architecture is a Web service which responds to HTTP GET or POST notifications, identifying the sensor provider who initiated the notification and the CARRE user to whom the data belongs. It invokes the relevant service corresponding to that provider, which then fetches that new data, converts it into RDF according to the schema described in Deliverable 2.4 and stores it in the CARRE semantic repository.

4.2.3. CARRE semantic repository

Each user in CARRE has a user account, and a private RDF graph on the semantic repository. The content of this graph is only accessible to that user and the CARRE system administrators. All data relating to that user is stored in the relevant private graph. User accounts and devices are managed through the CARRE Devices frontend⁵¹, which allows a user to add a connection to a new sensor data provider. Adding a connection involves authenticating with the appropriate sensor provider servers and retrieving authentication "tokens" which can be stored securely in the user's graph in the semantic repository. When this has been done, the

⁵¹ <u>https://carre.kmi.open.ac.uk/devices</u>



responder will receive notifications from that provider for that user, and will be able to retrieve the authentication tokens in order to fetch any newly added data.

4.2.4. Services

Each service, corresponding to a sensor data provider, follows the same general design. In particular, each service can:

- 1. Parse notifications from the relevant provider
- 2. Fetch appropriate authentication details for a user from the semantic repository⁵²
- 3. Fetch data from the provider corresponding to given date ranges or data identifiers.
- 4. Create appropriate representations of that data for converting to RDF.
- 5. Store RDF data in a user's private graph in the repository.

4.2.5. Metrics

Sensor data is represented generically by the metric components. Each type of metric is a generic type of sensor data – for example, blood pressure – generic across providers, rather than a specific component corresponding to, for example "Withings blood pressure" or "iHealth blood pressure". The services are able to invoke the metric component corresponding to a data type. The blood pressure metric, for example, requires values for systolic and diastolic blood pressure. Each metric can then generate the relevant RDF containing those values, for storing in the repository. This design ensures that different sensors which measure the same underlying biomarker data have their data represented in a common way. Because of the object-oriented design, the only occasions when a specific type of Metric such as Blood Pressure needs to be referenced is when actual data is being populated by the Service. For the most part, the generic superclass Metric is sufficient, and enables a high degree of component reuse.

4.2.6. Historical data retriever

In many cases during testing, users had been wearing and using sensors for some time before the personal sensor data aggregator had been fully implemented. The historical data retriever is designed to fetch data stored by any sensor providers from *before* the date a user connected that provider to CARRE. By default, data is fetched from the start date of the CARRE project. This process only applies to users who agree explicitly to their historical data being fetched.

4.2.7. CARRE Devices

The user interface to the aggregator is provided by a website which supports the creation and management of CARRE user accounts, and allows users to make connections between their accounts and various supported sensor data providers.

4.3. Personal sensor data aggregator implementation

The responder, services and metric components are all written in Java and run on the Tomcat servlet container⁵³.

⁵² Since providers do not all use the same authentication process, this is not a generic process, and must be customized for each provider.

⁵³ <u>http://tomcat.apache.org</u>



4.3.1. Responder implementation

The responder itself is a very thin layer which provides URLs to which each sensor provider can send notifications. For example, when new data is synced to Fitbit for a CARRE user, a notification is sent to:

https://carre.kmi.open.ac.uk/tomcat/responder/fitbit

whereas when data is synced to Withings, a notification arrives at:

https://carre.kmi.open.ac.uk/tomcat/responder/withings

and so on. By examining the particular URL to which the notification has been sent, the responder is able to identify which service to invoke. It passes the notification data to that service and returns an "OK" message to the sensor provider.

As stated above, nearly every sensor data provider has some form of notification mechanism. At the time of writing, the sole exception is Google Fit⁵⁴. To handle fetching data for Google Fit, the Unix task scheduling tool, cron, is used to trigger a poll frequently.

4.3.2. Service implementation

Each service is implemented as a subclass of a generic Service class in Java, and must implement two core methods⁵⁵:

- handleNotification
- getMetrics

The handleNotification method accepts HttpServletRequest and HttpServletResponse methods, which are passed directly from the responder and represent precisely the HTTP communication between the sensor provider and CARRE. Each service, within the handleNotification method, can extract the content of each notification. For example, a notification from Fitbit contains a JSON⁵⁶ message such as:

```
[
    {
        "collectionType":"activities",
        "date":"2014-10-01",
        "ownerId":"83CARRE",
        "ownerType":"user",
        "subscriptionId":"carreUser3",
    }
]
```

which signifies that new activity data has arrived relating to the Fitbit user account with identifier 83CARRE, and that this data belongs to a user on the CARRE system identified by carreUser3⁵⁷. The service therefore knows to fetch the Fitbit authentication tokens for the user identified by carreUser3, and to fetch activity data for the 1st of October 2014 from Fitbit. In particular, the service will then call getMetrics, passing date values to cover the 24 hour period of that date.

⁵⁴ <u>https://fit.google.com</u>

⁵⁵ Plus other methods related to housekeeping tasks.

⁵⁶ <u>http://www.json.org</u>

⁵⁷ The subscriptionId is simply a string unique for each user, and need not contain anything externally-identifying which could compromise privacy.



The getMetrics value accepts two date values, and returns a list of Metric objects representing the data stored for the current user with the current provider between those dates.

4.3.3. Metric implementation

Each Metric is implemented as a subclass of a generic Metric class in Java. Every Metric has an identifier (a string) and a date, intended to represent the date at which a measurement was taken. Each subclass of Metric must define a type (e.g., temperature).

Subclasses of Metric can vary significantly, depending on the individual type of measurement(s) represented. The Activity metric, for example, which is designed to represent the data collected by activity/fitness trackers, defines fields for steps taken, calories burned, the name of an activity (e.g., swimming) where logged, and so on. The BloodPressure metric defines fields for systolic and diastolic blood pressure values. Each particular type of Metric provides methods for getting and setting the values of each of its fields. The Service classes, when parsing data from a particular sensor provider, create instances of these Metric classes, and add values to their fields as appropriate.

The generic Metric class provides a method "toRDFString" which is passed a CARRE user identifier as a parameter. The user identifier is used to construct the base URL for the RDF representation of a Metric – an individual measurement is always given an HTTPS URL relative to the user's own RDF graph in the repository, to ensure uniqueness and security of identifiers across users.

The actual RDF triples corresponding to a particular measurement are constructed using the Java Reflection API⁵⁸, which can inspect classes, and the names of the fields in each class. Thus the Activity metric class, for example, has a field named "steps", and another named "sedentaryActivityDuration". Use of the Reflection API allows the construction of RDF predicates "has_steps" and "has_sedentary_activity_duration", respectively. By inspecting the *type* of each field, the appropriate types can be assigned to RDF literals representing the value of each field. So, for example, if "steps" is represented by a Java integer, a value for steps can be represented in RDF using the appropriate XML datatype⁵⁹ "integer".

The benefit of using Reflection to construct RDF is that the toRDFString method needs only be defined *once*, in the generic Metric class, with no need to rewrite, customize or specialize for any particular subclass. To ensure that the fields of a specific type of Metric are assigned the appropriate RDF representations, all that is needed is to ensure that the name of the corresponding Java field matches the desired representation.

The following example shows how straightforward it is to generate the RDF representation of a blood pressure measurement:

```
BloodPressure bp = new BloodPressure(identifier);
bp.setDate(measurementDate);
bp.setSystolicBloodPressure(systolicValue);
bp.setDiastolicBloodPressure(diastolicValue);
```

String rdf = bp.toRDFString(carreUserName);

This produces a set of RDF triples similar to the following:

⁵⁸ <u>http://docs.oracle.com/javase/7/docs/api/java/lang/reflect/package-summary.html</u>

⁵⁹ http://www.w3.org/TR/xmlschema11-2/



PREFIX carreUser:<https://carre.kmi.open.ac.uk/users/CARRE_USERNAME/measurements/>
PREFIX carreSensors:<http://carre.kmi.open.ac.uk/ontology/sensors.owl#>
PREFIX carreManufacturer:<http://carre.kmi.open.ac.uk/manufacturers/>
carreUser:b3bc5 carreSensors:has_date carreUser:b3bc5_date
carreUser:b3bc5_date carreSensors:has_value "2014-05-16T13:54Z"^^xsd:datetime
carreUser:b3bc5 carreSensors:is_measured_by carreManufacturer:ihealth

carreUser:b3bc5_carreSensors:has_blood_pressure_systolic carreUser:b3bc5_blood_pressure_systolic carreUser:b3bc5_blood_pressure_systolic carreSensors:has_value "122"^^xsd:integer carreUser:b3bc5_carreSensors:has_blood_pressure_diastolic carreUser:b3bc5_blood_pressure_diastolic carreUser:b3bc5_blood_pressure_diastolic carreSensors:has_value "88"^^xsd:integer

carreUser:b3bc5 carreSensors:has who b p level carreUser:b3bc5 who b p level

carreUser:b3bc5 who b p level carreSensors:has value "4"^^xsd:integer

which conforms to the RDF schema for measurements given in D.2.4.

4.3.4. Historical data retriever implementation

In order to support the notification mechanisms of each sensor data provider, the aggregator is, as discussed above, able to respond to HTTP messages of various formats which each, essentially, instruct the aggregator to fetch the data corresponding to a particular user for a particular date or date range. We take advantage of this mechanism in order to retrieve the historical data for each user.

When a sensor data provider is first connected to user's account, we store the date at which the connection was made. All data created *after* that date will of course be fetched by the aggregator. We have also stored the start date of the CARRE project (1st November 2013). By making use of the Unix cron task scheduler, periodically throughout the day, a "fake" notification will be sent to the aggregator, requesting the data for that user for that sensor provider for a fixed time period, beginning at the CARRE start date. Each time the task is run, it requests data for a later period, moving forward in time until it has reached the date on which the user connected that provider. At this point, the user's graph on the semantic repository will contain all data belonging to that user from the provider in question from the beginning of CARRE to the present date (or from the date the user first started gathering sensor data, if that date is later than the beginning of CARRE).

Users who do not wish to have older data fetched have the ability to disable this feature. It is enabled by default.

4.3.5. CARRE Devices implementation

The interface to the aggregator is provided by the CARRE Devices site, hosted at

https://carre.kmi.open.ac.uk/devices

The site is built in Python. The Dashboard, with which a user is introduced on the first logging in, presents icons for all of the supported sensor data providers (Figure 17). If the user clicks or taps on any one of them, (s)he will be led through the authentication process for that provider, and asked to approve the request from the CARRE aggregator to access data from the provider. The appropriate authentication details will then be stored in the user's graph on the semantic repository, allowing the aggregator to begin fetching new data as it arrives, and triggering the historical data fetching process.

For advanced users and developers, the site also provides a SPARQL search box, for querying.





Figure 17. The CARRE Devices Dashboard

4.3.6. Sequence diagrams for authentication and personal data retrieval from 3d party sensor clouds

Figure 18 shows sequence diagram of personal data retrieval from the iHealth cloud service. iHealth uses OAuth 2.0 authentication. The first step is the creation of the application within the iHealth cloud webpage which provides the developer with access credential. In the application, the developer also sets data aggregator web addresses and monitoring URL which empowers data collection on notifications (when new user data is available). When the CARRE sensor data aggregator (the "Web Service Application" of Figure 18). After certain amount of time, the access token may expire, thus it is constantly refreshed. The sequence diagrams of other cloud services which use OAuth 2.0 authentication (e.g. Misfit, GoogleFit support both OAuth 1.0a and OAuth 2.0) are similar except of the data names.





Figure 18. Sequence diagram of the iHealth personal data aggregator



Figure 19 shows sequence diagram of personal data retrieval from the Medisana cloud service. Medisana uses slightly modified OAuth 1.0a authentication which uses HMAC-SHA256 encryption instead of HMAC-SHA1. As in case with iHealth, the developer creates application within the Medisana cloud service page and receives the access credentials. Similarly, aggregator and notification URLs are set in the application form. After successful connection to the Medisana cloud service by aggregator web service application, personal data can be retrieved. The sequence diagrams for other vendors which support OAuth 1.0a (e.g. Withings, GoogleFit, Fitbit) authentication would be similar except the data names.

* 7	Web Servic	e Application Medisana Vit	adock Service
Developer User/	Patient		
Application Creation and Registration			
Create Application in Medisana Vitadock Portal		Receive Consumer Key & Secret]
Application is Created and Registered			
Start Authorization Sequence			
	Request Access to Protected Medisana Vitadock Resources .		
		Request for a Request Token	
		Receive a Reguest Token & Secret	
		Redirect to Authorization Endpoint	
		Log in or sign in page	
	Authoriz e Application		
		Receive Verifier Code (with Callback URL)	
		Request for the Access Token]
Authorization Is Completed		, ,	_
		Receive the Access Token & Secret	<u> </u>
Request for Data or Get New Data by Notific	ations		
		Get CardioDock data	1
		Return CardioDock data	
		Return GlucoDockGlucose data	
		Get GlucoDockInsulin data	
		Return GlucoDockInsulin data]
		Get GlucoDockl∨leal data	
		Return GlucoDockMeal data	_
		Return TargetScale data	
		Get ThermoDock data	
		Return ThermoDock data	
		Get TrackerStats data	7
		Return TrackerStats data	

Figure 19. Sequence diagram of the Medisana personal data aggregator



4.3.7. Code metrics

Table 12 shows code metrics of Django application tripleStore that implements the backend of CARRE sensors aggregator.

Table 12. Code metrics of tripleStore					
Python code metrics					
Lines of Code	2822				
Logical Lines of Code	2146				
Source Lines of Code	2342				
Number of Comment Lines	153				
Number of Lines Representing Multi-line Strings	33				
Number of Blank Lines	480				

Table 13 shows code metrics of Python code which is responsible for calling the responders and fetching historical data.

Table 13. Code metrics of historicalData				
Python code metrics				
Lines of Code	277			
Logical Lines of Code	190			
Source Lines of Code	232			
Number of Comment Lines	20			
Number of Lines Representing Multi-line Strings	0			
Number of Blank Lines	45			

Table 14 shows code metrics⁶⁰ of Java code for sensor aggregator responders.

Table 14. Code metrics of sensor aggregator responders		
Java code metrics		
Lines of Code	7148	
Method Hiding Factor	0,118	
Method Inheritance Factor	0,398	
Polymorphism Factor	0,167	

4.4. Hardware aggregator selection

The hardware aggregator must be either an Android tablet or smartphone. It cannot be an old device in order to be compatible with sensors' apps. Bluetooth v4.0 Low Energy (BLE) compatibility is crucial, since a number of proposed sensors are provided with BLE only. Large screen is preferred having in mind the ease of use, especially for elderly patients. It is expected that the price of the device should be about 300 EUR. Further on

⁶⁰ Calculating MOOD Metrics for Java, <u>http://poseidon.cs.uni-magdeburg.de/oomj/index_files/MOOD%20Java%20Assumptions.doc</u>



in this chapter we will discuss tablets and smartphones separately and choose one device in each category. We propose to use both, tablets and smartphones, and enable patient to choose the device which is the most suitable for him / her.

4.4.1. Tablets

The tablet would be the most suitable device because of the screen size. Mobile internet version is preferred in case a patient does not have a Wi-Fi network at home. However, most of the BLE compatible tablets are not cheap enough. Table 15 presents the chosen tablets for comparison that are available and suitable for the project.

Table 15. Tablets for the comparison of the price		
Model	Approximate price, EUR	
Samsung Galaxy Tab S 8.4 ⁶¹	440-490	
HTC Nexus 962	570	
Samsung Galaxy Tab 4 10.163	310	
Samsung Galaxy Tab 4 7.064	200	

As we can see, there are only two tablets in the expected price range. The main difference between them is the screen size. The 10.1 inch display is preferred. Therefore, the Samsung Galaxy Tab 4 10.1 LTE tablet is proposed to be used as the hardware aggregator in the project.

4.4.2. Smartphones

Smartphones, on the other hand, have their own advantages. They can be carried in the pocket all the time, thus ensuring more frequent health data updates from the sensors. Additionally, there are some smartphones with quite large displays (5-6 inch), which are sometimes even called "phablets". The price comparison of such smartphones is presented in Table 16.

Table 16. Smartphones for the comparison of the price		
Model	Approximate price, EUR	
Motorola Nexus 665	600	
Samsung Galaxy S466	300	
Samsung Galaxy Note 367	450	
Samsung Galaxy Note 3 Neo ⁶⁸	300	

In this case, again, two devices fall in the expected price range. The Galaxy Note 3 Neo is newer than Galaxy S4, has larger screen (5.5 inch vs. 5 inch). It is basically downgraded version of Galaxy Note 3. However, what is downgraded (0.2 inch smaller display, lower resolution, slightly slower processor) does not seem to affect

⁶¹ http://www.gsmarena.com/samsung_galaxy_tab_s_8_4_lte-6435.php (Last accessed 01/27/2015)

⁶² <u>http://www.gsmarena.com/htc_nexus_9-5823.php</u> (Last accessed 01/27/2015)

⁶³ <u>http://www.gsmarena.com/samsung_galaxy_tab_4_10_1_lte-6239.php</u> (Last accessed 01/27/2015)

⁶⁴ http://www.gsmarena.com/samsung_galaxy_tab_4_7_0_lte-6241.php (Last accessed 01/27/2015)

⁶⁵ http://www.gsmarena.com/motorola_nexus_6-6604.php (Last accessed 01/27/2015)

⁶⁶ <u>http://www.gsmarena.com/samsung_i9500_galaxy_s4-5125.php</u> (Last accessed 01/27/2015)

⁶⁷ http://www.gsmarena.com/samsung_galaxy_note_3-5665.php (Last accessed 01/27/2015)

⁶⁸ http://www.gsmarena.com/samsung_galaxy_note_3_neo-5961.php (Last accessed 01/27/2015)



performance required for the project and sensors' data aggregation. Therefore, the Samsung Galaxy Note 3 Neo is proposed to be used as the hardware aggregator in the project.



Annex 1 Sensor Aggregator Software



What is CARRE Sensor Data Aggregator?

The main goal of Sensor Data Aggregator is to integrate sensors data from data clouds of various manufacturers such as iHealth, Fitbit, Medisana, Misfit, Withings, Google Fit, to convert that data RDF triples and to store that RDF in the CARRE semantic repository.

The main parts of this aggregator are: the **Sensor Aggregator Responder**, the **Historical Data Retriever** and the **Triple Store**.

- The Sensor Aggregator Responder is a Web service which responds to HTTP GET or POST notifications, identifying the sensor provider who initiated the notification and the CARRE user to whom the data belongs. It invokes the relevant service corresponding to that provider, which then fetches that new data converts it into RDF and stores it in the CARRE semantic repository.
- The Historical Data Retriever is the historical data retriever designed to fetch data stored by sensor providers from before the date a user connected that provider to CARRE. By default, data is fetched from the start date of the CARRE project. This process only applies to users who agree explicitly to their historical data being fetched.
- The Triple Store is the Django application that implements the connection of sensors' manufacturers with CARRE's RDF repository (Virtuoso).

Download

Sensor Aggregator Responder v0.2:

- Source (687 KB): <u>CARRE_Sensor_Aggregator_Responders_v0.2.zip</u> (Java code)

download from https://carre.kmi.open.ac.uk/sites/default/files/sensor-aggregator-respondersand-metrics-source%202.zip

or from http://www.carre-project.eu/

- Source (363 KB): <u>SCRIBE Library_v1.3.3.jar</u> (Java binary)

download from https://carre.kmi.open.ac.uk/sites/default/files/scribe-1.3.3W.jar

or from http://www.carre-project.eu/

Historical Data Retriever v1.0:

- Source (4 KB): <u>CARRE_Historical Data Retriever.zip</u> (Python code)

download from https://carre.kmi.open.ac.uk/sites/default/files/historicalData.zip

or from http://www.carre-project.eu/

Triple Store v1.0:

Source (33 KB): <u>CARRE_Triple_Store.zip</u> (Python code)

download from https://carre.kmi.open.ac.uk/sites/default/files/tripleStore.zip

or from http://www.carre-project.eu/

Sensor Data Aggregator is Open Source

CARRE Sensor Data Aggregator is Open Source and can be freely used in Open Source applications under the terms GNU General Public License (GPL).

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