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## D.2.3. Data Source Identification and Description

VULSK, KTU, DUTH

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## **Executive Summary**

This deliverable contains the analysis of data sources related to CARRE goals and with respect to the use cases as defined in CARRE Deliverable D.2.1 and taking into account the functional requirements and CARRE information model as defined in D.2.2. It also identifies other relevant open data sources to be considered for metadata harvesting.

### 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 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 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.

ACCAmerican College of CardiologyADAAmerican Diabetes AssociationAHAAmerican Diabetes AssociationAPIApplication Programming InterfaceASAAmerican Stroke AssociationASNAmerican Stoke AssociationSNAmerican Society of NephrologyBIVABio impedance vector analysisBLEBluetooth Low EnergyBPMBeats Per MinuteBRBreath RateCDSRCochrane Database of Systematic ReviewsCKDChronic kidney diseaseCKDChronic kidney diseaseCVDCardiovascular diseaseDCDirect CurrentEBMEvidence based medicineEBSCOElectroardiographyECGElectroardiographyECGElectronic Health RecordEMRElectronic Patient RecordENOPEEuropean Network on Patient EmpowermentEPRElectronic Patient RecordENOPEEuropean Network on Patient EmpowermentEPRElectronic Patient RecordEVAFood Drug AdministrationGDAFood Drug AdministrationGPRSGlobal System for Mobile CommunicationsHDLHigh density lipoprotein	Term	Definition	
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EBSCOElton B Stephens CompanyECGElectrocardiographyECWExtracellular waterEDREnhanced Data RateEHRElectronic Health RecordEMGElectronic Medical RecordENOPEEuropean Network on Patient EmpowermentEPRElectronic Patient RecordEUEuropean Network on Patient ServicesEUEuropean UnionFDAFood Drug AdministrationGPRSGeneral Packet Radio ServiceGSMGlobal Positioning SystemGSMGlobal System for Mobile Communications	DC	Direct Current	
ECGElectrocardiographyECWExtracellular waterEDREnhanced Data RateEHRElectronic Health RecordEMGElectromyographyEMRElectronic Medical RecordENOPEEuropean Network on Patient EmpowermentEPRElectronic Patient RecordepSOSEuropean Patients - Smart open ServicesEUEuropean UnionFDAFood Drug AdministrationGPRSGeneral Packet Radio ServiceGPSGlobal Positioning SystemGSMGlobal System for Mobile Communications	EBM	Evidence based medicine	
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EUEuropean UnionFDAFood Drug AdministrationGPRSGeneral Packet Radio ServiceGPSGlobal Positioning SystemGSMGlobal System for Mobile Communications	EPR	Electronic Patient Record	
FDAFood Drug AdministrationGPRSGeneral Packet Radio ServiceGPSGlobal Positioning SystemGSMGlobal System for Mobile Communications	epSOS	European Patients - Smart open Services	
GPRS       General Packet Radio Service         GPS       Global Positioning System         GSM       Global System for Mobile Communications	EU	European Union	
GPS     Global Positioning System       GSM     Global System for Mobile Communications	FDA	Food Drug Administration	
GSM Global System for Mobile Communications	GPRS	General Packet Radio Service	
	GPS	Global Positioning System	
HDL High density lipoprotein	GSM	Global System for Mobile Communications	
	HDL	High density lipoprotein	



HFA of the ESC	Heart Failure Association of the European Society of Cardiology	
HIS	Hospital information system	
HISA	Health Informatics Service Architecture	
HL7	Health Level Seven International	
HL7 FHIR	Health Level Seven International Fast Healthcare Interoperability Resources	
HONcode	Health On the Net Code	
HR	Heart Rate	
HRV	Heart Rate Variability	
ICT	Information and communications technology	
ICD9	International Statistical Classification of Diseases and Related Health Problems 9th Revision	
ICD10	International Statistical Classification of Diseases and Related Health Problems 10th Revision	
ICW	Intracellular water	
IDF	International Diabetes Federation	
IPK	Internet Patient History	
ISO	International Organization for Standardization	
ISO/TC	International Organization for Standardization's Technical Committee	
LAN	Local Area Network	
LDL	Low density lipoprotein	
LED	Light Emitting Diode	
LOINC	Logical Observation Identifiers Names and Codes	
MeSH	Medical Subject Headings, http://www.ncbi.nlm.nih.gov/mesh	
MDRD	Modification Of Diet in Renal Disease	
NCBI	The National Center for Biotechnology Information	
NDC	National Drug Code	
NDIC	National Diabetes Information Clearinghouse	
NFC	Near Field Communication	
NIDDKD	National Institute of Diabetes and Digestive and Kidney Disease	
NIH	National Institutes of Health	
NKDEP	National Kidney Disease Education Program	
NLM	National Library of Medicine	
OCEBM	Centre for Evidence-based Medicine at the University of Oxford	
OEM	Original equipment manufacturer	
OLED	Organic Light Emitting Diode	
OpenEMPI	Open Enterprise Master Patient Index	
PHR	Personal Health Record	
PPG	Photoplethysmography	



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RAM	Random Access Memory	
RXCUI	RxNorm Concept Unique Identifier	
RF	Radio Frequency	
SDK	System Development Kit	
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms	
SpO2	Peripheral capillary oxygen saturation	
SPP	Serial Port Profile	
SPS	Samples Per Second	
SOA	Service Oriented Architecture	
TBW	Total body water	
TRIP	Turning Research Into Practice	
URL	Uniform resource locator	
U.S.	United States	
USB	Universal Serial Bus	
VULSK	Vilnius University Hospital Santariškių Klinikos	
WHO	World Health Organization	
WIN	Weight Control Information Network	
XML	Extensible Markup Language (XML) is a markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.	



## 1. Introduction

The document contains a detailed analysis of the data sources, which were previously defined by CARRE project in respect to the use cases defined in T.2.1 and functional requirements and CARRE information model defined in T.2.2. In addition, open data sources used for metadata harvesting and data sources required for personalized patient empowerment and decision support services are described.

Section 2 provides brief information on conditions and comorbidities related to cardiorenal syndrome and possible personal sensors used to monitor various health observables. Relevant sensors are thoroughly categorized in terms of observables/conditions monitored and detailed technical specification as well as application modality is provided.

Section 3 contains a short definition of medical information stored in electronic format: electronic health record (EHR), electronic medical record (EMR), personal health record (PHR), key differences among them, standards used to maintain data interoperability as well as privacy and ethical considerations are described. Currently available sources of PHR are also overviewed.

In Section 4, sources of patient related information on the internet are described, focusing on popular social media tools.

Section 5 provides information on sources of current best medical evidence, its selection criteria and ranking. This section also contains some ethical considerations in terms of usage of evidence based data information in clinical practice. Sources of evidence-based information are also described.

Sources of patient empowerment, education and decision support are provided in Section 6. Online patient education material is described based on specific data source selection criteria and applicable medical condition or comorbidity.

All URLs in the document were last accessed within July 2014 (unless otherwise stated), and prices quoted are market prices for July 2014.

## 2. Sources of Personalized Real-Time Data on Health Status & Lifestyle

## 2.1. Personal biomarkers derived from domain analysis

CARRE project report "D.2.2. Functional Requirements & CARRE Information Model" resulted into the descriptions of risk elements in Table 3 and medical observables in Table 4. Table 4 points out a type for each observable - either clinical or personal. This information serves as a beacon for selection of data sources in this chapter.

The Table 1 below lists the subset of all identified observables - only those that can be monitored by the patients themselves at home (labelled as "Personal" in D.2.2: Table 4). The report defines additional criteria for data sources selection (Chapter 2.2), shows if and what commercial devices are available for project CARRE purposes (Chapters 2.3-2.6), what sensors do not exist and what possible research and development directions could be followed to fill the gaps (Chapter 2.7).

Table 1. Subset of CARRE Risk elements and Observables relevant for personal monitoring at home					
Group	Risk elements	Observables			
Cardiovascular	Hypertension	Systolic blood pressure, diastolic blood pressure			
	Hypotension	Systolic blood pressure, diastolic blood pressure			
	Atrial fibrillation	ECG, HR			



	Heart failure	Body fluids
Metabolic	Obesity	Body weight, body mass index, body fat
	Diabetes	Fasting plasma glucose levels
Lifestyle	Sedentary lifestyle	Physical activity

## 2.2. Data source selection criteria

The following criteria for data sources selection were considered:

- 1) Relevance to the application of CRS monitoring;
- 2) Accuracy and precision;
- 3) Reliability (materials, robustness, waterproofness);
- 4) Sensor comfort ability (easy to use, unobtrusiveness, longevity of battery life);
- 5) Exploitation expenses (disposables);
- 6) Availability of application interface (API);
- 7) Direct data availability via standard (e.g. Continua Alliance Bluetooth HDP) or proprietary protocols based wireless (e.g. WiFi, Bluetooth) or USB connection;
- 8) Cloud based data availability via open API and secure connection to service provider WEB data repository;
- 9) Support of Google Android, Apple iOS and Microsoft Windows Phone mobile devices; and
- 10) Price.

## 2.3. Cardiovascular state monitoring

Observables as identified in D.2.2 that are directly related to cardiac group of cardiorenal syndrome conditions and that can be monitored by the personal sensors are:

- Blood pressure (BP);
- Heart rate (HR);
- Electrocardiogram (ECG); and
- Blood oxygenation (SpO2).

### 2.3.1. Commercial devices identification and description

#### 2.3.1.1. Blood pressure

#### QardioArm Wireless Blood Pressure Monitor by Qardio

QardioArm<sup>1</sup> (see Figure 1) is smart wireless blood pressure monitor that measures and records systolic and diastolic blood pressure and heart rate readings.

<sup>&</sup>lt;sup>1</sup> <u>https://www.getqardio.com/</u>





Figure 1. CardioArm Wireless Blood Pressure Monitor1,2

Main features and specifications:

- Accurate and clinically validated.
- CE-mark approved for use by medical professionals, patients and health aware users.
- Irregular heart beat detection.
- Gentle and comfortable automatic inflation.
- Light, compact and portable (140x38x68 mm, 310 g).
- Wireless connection (Bluetooth 4.0) to your smartphone or tablet: simple, intuitive setup.
- Works With: iPhone 4S or later, iPad 3rd generation or later, iPad Air, iPad mini, iPod touch 5th generation or later. Requires Bluetooth 4.0 and iOS 7.0 or later. Free Qardio app (available for download on the App Store).
- Records blood pressure readings and uploads them to the cloud.
- Measurement: oscillometric method with automatic inflation and controlled pressure release valve.
- Measurement Range: 40~250 mmHg for blood pressure 40~200 beats/minute for pulse.
- Measurement Resolution: 1mmHg for blood pressure; 1 beat/min for pulse.
- Fits most users (cuff size 22-37cm).
- Low power consumption: one set of batteries typically lasts one year (4xAAA batteries).
- Price: 109 EUR.

#### Beurer blood pressure monitors

Beurer<sup>3</sup> offers range of blood pressure monitors with wireless communication:

- Model BM 75<sup>4</sup> (Figure 2, left).
- Model BM  $85^5$  (Figure 2, center).
- Model BM 90<sup>6</sup> (Figure 2, right).

<sup>&</sup>lt;sup>2</sup> <u>http://tctechcrunch2011.files.wordpress.com/2014/01/qardioarm.jpg?w=580</u>

<sup>&</sup>lt;sup>3</sup> <u>http://www.beurer.com</u>

<sup>&</sup>lt;sup>4</sup> <u>http://www.beurer.com/web/en/products/bloodpressure/upper\_arm/BM-75</u>

<sup>&</sup>lt;sup>5</sup> http://www.beurer.com/web/en/products/bloodpressure/upper\_arm/BM-85

<sup>&</sup>lt;sup>6</sup> http://www.beurer.com/web/en/products/bloodpressure/upper\_arm/BM-90





Figure 2. Beurer blood pressure monitors: Model 75 (left)<sup>4</sup>, Model 85 (center)<sup>5</sup> and Model 90 (right)<sup>6</sup>

Main features and specifications:

- New: available from January 2014 (BM 75), April 2014 (BM 85)
- Fully-automatic measurement on the upper arm
- Measurement range:
  - o systolic 30–280 mmHg
  - o diastolic 30-280 mmHg
  - pulse 40–199 beats per minute
- Measurement inaccuracy: max. permissible standard deviation according to clinical testing: systolic 8 mmHg/diastolic 8 mmHg
- Arrhythmia detection: warning in case of possible heart rhythm disturbance
- Medical product
- Wireless/PC communication:
  - Model BM 75: transfer using NFC technology, transfers blood pressure measurements to smartphones compatible with NFC at a distance of a few centimetres; NFC device model in accordance with ISO 15693 and ISO 18000-3) and USB
  - Model BM 85: Bluetooth 4.0 (supported by iOS and Android 4.3 (and up) smartphones)
  - Model BM 90: short range RF 868MHz communication to the wireless box with LAN connection (wireless box connects directly to web service)
- Patented resting indicator for exact measurement results
- Free Beurer software "Health Manager"7 what have connection with Microsoft HealthVault8 webbased platform from Microsoft to store and maintain health and fitness information
- 2 x 60 memory spaces
- WHO classification
- Battery life (4xAA batteries):
  - Model BM 90:for approx. 120 measurements, depending on levels of blood pressure and pump pressure
- Prices:
  - 90 EUR for Model BM75
  - o 105 EUR for Model BM85
  - 120 EUR for Model BM90

<sup>&</sup>lt;sup>7</sup> <u>https://connect.beurer.com/Download/Start.aspx</u>

<sup>&</sup>lt;sup>8</sup> <u>https://www.healthvault.com/</u>



#### iHealth Labs blood pressure monitor

iHealth Labs offers three blood pressure monitors: Wireless Blood Pressure Wrist Monitor BP7<sup>9</sup> (Figure 3, left), Wireless Blood Pressure Monitor BP5<sup>10</sup> (Figure 3, right) and Blood Pressure Dock<sup>11</sup> (Figure 4). All of them are fully automatic cuff blood pressure monitors that use the oscillometric principle to measure blood pressure and pulse rate. The monitors work with mobile devices to test, track and share vital blood pressure data. The Blood Pressure Dock works with only iOS device that should be docked into the monitor to test, track and share vital blood pressure data.



Figure 3. iHealth's Wireless Blood Pressure Wrist Monitor BP7 (left)<sup>12</sup> and Wireless Blood Pressure Monitor BP5 (right)<sup>10</sup>



Figure 4. iHealth Blood Pressure Dock<sup>11</sup>,<sup>13</sup>

Main features and specifications:

- Wireless communication: Bluetooth V3.0+EDR Class 2 SPP (for BP7 and BP5)
- Measuring method: Oscillometric, automatic inflation and measurement
- Power: DC:5.0V, Battery: 1\*3.7V Li-ion 400mAh (more than 1,000 readings can be taken with one set of batteries)
- Cuff pressure range: 0-300mmHg
- Systolic blood pressure: 60-260 mmHg
- Diastolic blood pressure: 40-199 mmHg
- Pressure accuracy: ±3mmHg
- Pulse rate range: 40 -180 beats/min, accuracy: ±5%

<sup>&</sup>lt;sup>9</sup> <u>http://www.ihealthlabs.eu/wireless-blood-pressure-wrist-monitor-feature\_33.htm</u>

<sup>&</sup>lt;sup>10</sup> <u>http://www.ihealthlabs.eu/wireless-blood-pressure-monitor-feature\_32.htm</u>

<sup>&</sup>lt;sup>11</sup> <u>http://www.ihealthlabs.eu/blood-pressure-dock-feature\_31.htm</u>

<sup>&</sup>lt;sup>12</sup> <u>http://www.lidtmere.dk/media/catalog/product/cache/4/thumbnail/336x/9df78eab33525d08d6e5fb8d27136e95/w/i/wireless\_blood\_pressure\_wrist\_monitor\_3\_1.jpg</u>

<sup>&</sup>lt;sup>13</sup> <u>http://www.ihealthlabs.eu/images/products/pro31\_1.jpg</u>



- Free iHealth MyVitals mobile app is available for iPhone, iPad or iPod touch and for Android. iHealth
  Labs application automatically transfers data to the cloud enabled service
  <a href="https://cloud.ihealthlabs.com">https://cloud.ihealthlabs.com</a>, using which consumers are able to see a more comprehensive view of
  their vitals and easily share information with healthcare professionals or others.
- Prices:
  - 80 EUR (Wireless Blood Pressure Wrist Monitor)
  - 71 EUR (Blood Pressure Dock)
  - 100 EUR (Wireless Blood Pressure Monitor)

### Withings Blood Pressure Monitor

Wireless blood pressure monitor by Withings<sup>14</sup> (Figure 5) has wireless (Bluetooth) and wired (USB) connectivity.



Figure 5. Withings Wireless Blood Pressure Monitor<sup>14</sup>

Main features and specifications:

- Cuff oscillometric method
- Wireless connectivity: Bluetooth 4.0
- Pressure Measurement range: 0 to 285 mmHg, accuracy: ±3 mmHg or 2% of reading
- Heart rate measurement range: from 40 to 180 beats per minute, accuracy: 5% of reading
- Automatic inflation / Controlled release
- Compliant with European medical device regulations and has received clearance from the Food and Drug Administration (FDA) in the USA.
- Power 4xAAA alkaline batteries
- Compatible with: iOS 6 or higher and Android 4.0 or higher smartphone or tablet with Bluetooth compatibility and Internet connectivity (cellular data or Wi-Fi). App not tablet optimized. Data storage in Withings HealthCloud. Also compatible with some others apps (TicTrac, Carepass, GenieMD, ovia). Has API: http://oauth.withings.com/api
- Price: 130 EUR

### Medisana Blood Pressure Monitor

Medisana offers range of blood pressure monitors for mobile health<sup>15</sup>. Part of them have wired connectivity (models CardioCompact, MTX – Figure 6), others are designed as dock stations for Apple smart phones (models CardioDock® Blood pressure module, CardioDock® 2 Blood Pressure Module – Figure 7) and others

<sup>&</sup>lt;sup>14</sup> <u>http://www.withings.com/eu/blood-pressure-monitor.html</u>

<sup>&</sup>lt;sup>15</sup> <u>http://www.medisana.com/en/Mobile+Health/Blood+pressure+monitor/</u>



have wireless Bluetooth connectivity (models BW 300 connect Wrist, BU 575 connect, BU 550 connect – Figure 8).



Figure 6. USB connectivity blood pressure monitors: CardioCompact (left)<sup>16</sup> and MTX (right)<sup>17</sup>



Figure 7. Dock type blood pressure monitors for Apple smart phones and tablets: CardioDock® Blood pressure module (left)<sup>18</sup>, CardioDock® 2 Blood Pressure Module (right)<sup>19</sup>



Figure 8. Wireless Blood Pressure Monitors with Bluetooth: BW 300 connect Wrist (left)<sup>20</sup>, BU 550 connect Upper arm (center)<sup>21</sup>, BU 575 connect Upper arm (right)<sup>22</sup>

Main features and specifications of Medisana blood pressure monitors:

- Oscillometric measurement method
- Wireless models offer faster measurement results thanks to inflation technology the blood pressure is measured during the inflation of the cuff
- Measurement range:
  - Blood pressure: 30-280 (40 260 mmHg for CardioCompact)
  - Pulse: 40-200 beats/min (40 180 beats/min for CariodCompact)

<sup>&</sup>lt;sup>16</sup> <u>http://www.greenweez.com/images/products/26000/600/medisana-tensiometre-cardiocompact-2-en-1.jpg</u>

<sup>&</sup>lt;sup>17</sup> http://www.medpharm.com.my/wp-content/uploads/2012/10/51080-MTX.jpg

<sup>&</sup>lt;sup>18</sup> <u>http://www.medisana.com/out/pictures/generated/product/2/550\_550\_80/51281\_cardiodockde03.jpg</u>

<sup>&</sup>lt;sup>19</sup> <u>http://www.planete-domotique.com/media/catalog/product/v/d/vd51285\_1.jpeg</u>

<sup>&</sup>lt;sup>20</sup> http://www.medisana.com/out/medisana/img/connect/bw300/Banner\_EN.png

<sup>&</sup>lt;sup>21</sup> http://www.medisana.com/out/medisana/img/connect/bu550/Banner\_EN.png

<sup>&</sup>lt;sup>22</sup> http://www.medisana.com/out/medisana/img/connect/bu570/Banner\_EN.png



- The approval according to the Medical Device Directive confirms the secure and precise measurement
- Compatibility with iOS, Android and Windows
- Transfer of measurements results to the cloud VitaDock Online23
- Price:
  - 45 EUR for CardioCompact
  - o 85 EUR for MTX
  - 139 EUR for CardioDock
  - 130 EUR for CardioDock 2
  - 80 EUR for BW300
  - 90 EUR for BU 550
  - 100 EUR for BU 575

#### 2.3.1.2. Heart rate

Heart rate measurements are performed by measuring: heart biopotentials, blood pressure fluctuations or photoplethysmogram. In addition, heart rate as observable can be measured in various conditions: in rest (then it is also measured together with blood pressure, blood oxygenation and rest ECG measurements) and in daily physical activity (in this case it can be measured during registration of physical activity ECG). For exercise heart rate measurements the most wide spread method is the biopotential based chest strap method. The new direction is photoplethysmography based heart rate acquisition devices, having capability to obtain heart rate using photo sensor placed on hand. Heart rate measurement device choice also depends on the required further analysis of heart rate data: is heart rate variability analysis required or not.

#### eMotion HRV

eMotion HRV<sup>24</sup> (Figure 9) is a product of Mega Electronics Ltd for heart rate variability measurements for the use in research, wellness, exercise and in top sports. eMotion HRV offers long-term measurements, advanced automated analyses, easy-to-understand reports and versatile analysis tools for research.

Main features and specifications:

- Weight: 16 g
- Dimensions: 35 mm x 35 mm x 15 mm
- Battery: Rechargeable Li-Ion battery
- Battery life: over 96 hours
- Charging: Charger dock or USB interface
- Capacity of internal memory:
  - HRV: 5 days measurement
  - HRV 3D: 1 day measurement
- Connection to PC: USB
- Heart rate variability measurement:
  - Sampling frequency: 1000 Hz, Accuracy: 1 ms
- Acceleration (only with HRV 3D model): 10 Hz each axis

<sup>&</sup>lt;sup>23</sup> <u>https://cloud.vitadock.com/</u>

<sup>&</sup>lt;sup>24</sup> <u>http://www.megaemg.com/products/emotion-hrv/</u>



- Less artefacts than in chest strap measurements
- Superior conductivity between skin and sensor
- No need for wrist top computer
- Unnoticeable during daily life
- Price: 587 EUR

eMotion LAB software is used for downloading, viewing and easy exporting of HRV data. eMotion HRV data can also be analysed with other software: Kubios HRV (freeware), Firstbeat SPORTS, Firstbeat HEALTH.



Figure 9. eMotion HRV<sup>24</sup>

#### Zephyr heart rate monitoring products

Zephyr<sup>25</sup> offers three devices for the heart rate and activity monitoring: BioHarness 3 Model BH3<sup>26</sup> heart, HxM Smart heart rate monitor<sup>27</sup> and HxM BT heart rate monitor<sup>28</sup>.

BioHarness 3 Model BH3 device (Figure 10, top) is the compact physiological monitoring module that enables the capture and transmission of physiological data on the wearer via mobile and fixed data networks. BioHarness was widely used in research studies<sup>29</sup>. The main features and specifications of the device are:

- Wireless communication: Bluetooth
- Measured parameters: heart rate, R-R interval, breathing rate, posture, activity level, peak acceleration, speed & distance with GPS (optional)
- Machine Washable strap that offers both comfort and accuracy
- Long transmission range (~300ft up to ~1000ft (w/Antenna & Amplifier))
- Water Resistant up to 1m
- Logs and stores up to 20 days of data
- HR Range: 25 240 BPM
- BR Range: 4-70 BPM
- Acc. Range: ±16g
- Battery Life (Li-ion): 26 Hours per charge
- Charge Cycles: 300
- Garment Washes: 80
- Price: 594 EUR (550 USD)

<sup>&</sup>lt;sup>25</sup> <u>http://zephyranywhere.com/products/</u>

<sup>&</sup>lt;sup>26</sup> <u>http://zephyranywhere.com/products/bioharness-3/</u>

<sup>&</sup>lt;sup>27</sup> <u>http://zephyranywhere.com/products/hxm-smart-heart-rate-monitor/</u>

<sup>&</sup>lt;sup>28</sup> <u>http://zephyranywhere.com/products/hxm-bluetooth-heart-rate-monitor/</u>

<sup>&</sup>lt;sup>29</sup> <u>http://zephyranywhere.com/zephyr-labs/white-papers/</u>





Figure 10. BioHarness 3 device (top)<sup>30</sup> and HxM BT/Smart device (bottom)<sup>31</sup>

HxM BT and HxM Smart are similar devices (Figure 10, bottom), that captures heart rate and activity using smart fabric chest strap. Differences between them are in wireless communication module – Bluetooth v2.0 for BT and Bluetooth v4.0 for Smart. Communication module difference leads to the difference in power consumption (see specifications below).

HxM Smart features and specifications:

- Wireless communication: Bluetooth Smart (Low-Energy)
- Machine Washable strap that offers both comfort and accuracy
- Water Resistant up to 1m
- Supported by dozens of Apps
- Works with iPhone 4S, iPhone 5, iPod touch (5th generation), iPad (3rd & 4th generation), iPad mini and iPod Nano (7th generation), Android 4.3 (where available)
- Measured parameters: heart rate, heart rate variability, R-R interval, stress level, activity level, peak acceleration, calories (depends on apps)
- HR Range: 25 240 BPM
- Battery Type: CR2032 (battery life 150 hours)
- Transmit Range: 10m
- Garment Washes: 50
- Price: 70 EUR (55 USD)

HxM BT features and specifications:

- Wireless communication: Bluetooth v2.0 SPP for Android and Windows Phone 8 devices
- Machine Washable strap that offers both comfort and accuracy
- Water Resistant up to 1m
- Supports dozens of Apps with no subscriptions required
- Measured parameters: heart rate, R-R interval, speed and distance (algorithm-derived)

<sup>&</sup>lt;sup>30</sup> <u>http://zephyranywhere.com/wp-content/uploads/img\_BioHarness\_Assembly2.jpg</u>



- HR Range: 25 240 BPM
- Battery Type: Rechargeable Lithium Polymer
- Battery Life: 26 Hours per charge
- Garment Washes: 50
- Price: 100 EUR (75 USD)

All three modules have free software development tools<sup>31</sup> for Android (BioHarness and HxM BT/Smart) and iOS (HxM Smart).

#### Polar heart rate monitors

Polar offers range of chest strap heart rate sensors<sup>32</sup> for sport activities. From the all range of sensors, the most attractive are two models: H6<sup>33</sup> and H7<sup>34</sup> sensors (Figure 11). They have soft strap, Bluetooth Smart wireless transmission, are compatible with iPhone 4s and the later with Android 4.3 or later devices and its standardized heart rate analysis service. Model H7 also has GymLink communication (5 kHz transmission), used for transmission while swimming.



Figure 11. Polar H6<sup>35</sup> (left) and H7<sup>36</sup> (right) heart rate sensors with Bluetooth Smart (v4.0)

Main specifications:

- Battery type CR 2025
- Battery lifetime 300 h (H6) and 200 h (H7)
- Price: 60 EUR (H6); 70 EUR (H7)

Polar H7 has been reported<sup>37</sup> as the good device for assessing heart rate variability comparing with HRV obtained with reference ECG (correlation of results 0,97-0,99).

#### Other chest strap heart rate sensors

There are also a few other producers of chest strap based heart rate monitors with wireless connectivity. Below are presented some more examples.

Armour39<sup>38</sup> (by Under Armour, see Figure 12) is performance monitor that tracks heart rate, calories, realtime intensity, and so called WILLpower<sup>™</sup> (measure of an athlete that boils workout down to a single score 1.0-10.0). This device, unlike other heart rate monitors that only average your heart rate data, precisely captures every heartbeat. The device uses Bluetooth smart for wireless communication and is compatible with iPhone 4s and later and (possibly) with Android 4.3 or later. This device was tested for suitability for

<sup>&</sup>lt;sup>31</sup> <u>http://zephyranywhere.com/zephyr-labs/</u>

<sup>&</sup>lt;sup>32</sup> http://www.polar.com/en/products/accessories/

<sup>&</sup>lt;sup>33</sup> <u>http://www.polar.com/en/products/accessories/H6 heart rate sensor</u>

<sup>&</sup>lt;sup>34</sup> <u>http://www.polar.com/en/products/accessories/H7\_heart\_rate\_sensor</u>

<sup>&</sup>lt;sup>35</sup> <u>http://www.thegearcaster.com/gcimages/6a01156f7533eb970c017d3fb9a90f970c-500wi</u>

<sup>&</sup>lt;sup>36</sup> <u>http://www.polar.com/sites/default/files/h7\_heart\_rate\_sensor\_newcolors2\_240x298\_0.png</u>

<sup>&</sup>lt;sup>37</sup> http://www.marcoaltini.com/blog/heart-rate-variability

<sup>&</sup>lt;sup>38</sup> <u>http://www.underarmour.com/shop/us/en/armour39-module-and-strap/pid1255371-001</u>



HRV tests by Marco Altini<sup>39</sup> and showed good correlation (slightly less than Polar H7) with the reference HRV results obtained using ECG: 0,95-0,98. Price: 110 EUR.



Figure 12. Armour39 heart rate chest strap<sup>38</sup>

Garmin<sup>40</sup> offers heart rate monitors<sup>41</sup> using ANT+ wireless technology, supported by some smart phones. The prices of Garmin's products are about 60 EUR.

Wahoo Fitness<sup>42</sup> offers Tickr and Tickr Run devices (Figure 13) that tracks heart rate and calories burned in real-time. Tickr Run also has accelerometer that is used for running smoothness assessment. Both devices have ANT+ and Bluetooth Smart wireless capability and work with iOS and Android devices. Tickr is sold for 60 EUR and Tickr Run – for 80 EUR.



Figure 13. Wahoo Fitness Tickr Heart Rate Monitor<sup>43</sup>

Runtastic<sup>44</sup> offers Heart Rate Combo Monitor (Figure 14, left) that uses the latest Bluetooth® Smart wireless technology to transfer heart rate data. The Heart Rate Monitor also has a 5.3 kHz signal transfer, which allows it to work with most cardio equipment in the gym (e.g. treadmill). Compatible with iOS and Android smart phones. Device is using CR2032 battery. Price: 70 EUR.



Figure 14. Runtastic Heart Rate Combo monitor<sup>45</sup> (left), Jarv Premium Bluetooth 4.0 Smart Heart Rate monitor<sup>46</sup> (right)

<sup>&</sup>lt;sup>39</sup> <u>http://www.marcoaltini.com/blog/heart-rate-variability</u>

<sup>&</sup>lt;sup>40</sup> http://www.garmin.com/

<sup>&</sup>lt;sup>41</sup> https://support.garmin.com/search/shopResults.faces?site=Shop&filter=0&client=garmin\_fe&g= heart+rate &Go=

<sup>&</sup>lt;sup>42</sup> http://eu.wahoofitness.com/devices/hr.html

<sup>&</sup>lt;sup>43</sup> <u>http://assets.hardwarezone.com/img/2014/06/Wahoo\_FitnessTickr\_news.jpg</u>

<sup>44</sup> www.runtastic.com

<sup>&</sup>lt;sup>45</sup> <u>http://media.engadget.com/img/products/483/adas/adas-800.jpg</u>

<sup>&</sup>lt;sup>46</sup> <u>http://www.mobilecityonline.com/images/extra/32262 L 22617.jpg</u>



Jarv Mobile for 90 EUR offers Jarv Premium Bluetooth 4.0 Smart Heart Rate Monitor<sup>47</sup>. Monitor uses Bluetooth 4.0 BLE technology to transmit accurate real-time heart rate data. Works with most Android devices using OS version 4.3 or later and apps using the latest BLE (Bluetooth Low Energy) technology. Device also uses CR2032 battery. Adidas also offers Bluetooth Low Energy (4.0) based chest strap monitors HRM BTLE<sup>48</sup> (61 EUR) and X\_CELL<sup>49</sup> (54 EUR, also includes accelerometer). Device uses CR2032 battery, runs 300 hours, automatically activates or deactivates, has connectivity to iOS and Android devices.

#### Monitoring heart rate using smart phone camera

Monitoring heart rate using mobile phone camera is widely explored in smart phone apps. Accuracy of such measurements highly depends on algorithms implemented in apps, but such approach potentially has been shown<sup>50,51</sup> to be in favourably agreement with ECG based measurements. Study of *Mathew at all, 2012* showed that heart rate measurements using Motorola's Droid "provided accuracy similar to the FDA-approved (K081285, 2008) and ISO 9919 compliant, Nonin Onyx II model 9560BT ambulatory finger pulse oximeter". Marco Altini showed<sup>52</sup> that software application CameraHRV written by him for iPhone can capture heart rate variability in high correlation (ranging from 0,78 to 0,99 for various HRV analysis results) to those obtained by chest strap (Polar H7). The author also mentioned tips for correct HR measurement: use your fingertip; place your fingertip exactly on the camera, you need to cover it all; do touch the camera, but limit pressure (it's important to touch it gently, otherwise too much pressure will impede blood flow (which is what needs to be measured)); try to record using 60 seconds windows. Research on ultra-short term HRV showed that all features can be reliably measured in 50 seconds (LF and HF included).



Figure 15. Heart rate measurement apps using mobile phones camera<sup>53</sup>

The recently (February 2014) announced smart phone by Samsung – Galaxy S5<sup>54</sup> includes integrated heart rate sensor: red LED and photo-pulse sensor.

<sup>49</sup> <u>https://micoach.adidas.com/nl/x\_cell</u>

<sup>&</sup>lt;sup>47</sup> <u>http://www.jarvmobile.com/productdetail.asp?productid=33499</u>

<sup>&</sup>lt;sup>48</sup> <u>https://micoach.adidas.com/nl/heartratemonitor</u>

<sup>&</sup>lt;sup>50</sup> Scully C.G, Lee J.S, Meyer J, Gorbach A.M, Granquist-Fraser D, Mendelson Y,Chon K.H. Physiological Parameter Monitoring from Optical Recordings With a Mobile Phone", IEEE Transactions. Biomedical Engineering. 2012; 59(2).303-306.

<sup>&</sup>lt;sup>51</sup> J. Gregoski M. J, Mueller M, Vertegel A, et *al.* Development and Validation of a Smartphone Heart Rate Acquisition Application for Health Promotion and Wellness Telehealth Applications. International Journal of Telemedicine and Applications, 2012, vol. 2012, Article ID 696324, 7 p., doi:10.1155/2012/696324

<sup>&</sup>lt;sup>52</sup> <u>http://www.marcoaltini.com/blog/heart-rate-variability-using-the-phones-camera</u>

<sup>&</sup>lt;sup>53</sup> <u>https://play.google.com/store/apps/details?id=si.modula.android.instantheartrate&hl=lt</u>

<sup>&</sup>lt;sup>54</sup> http://www.samsung.com/global/microsite/galaxys5/features.html





Figure 16. Samsung Galaxy S5 with integrated heart rate sensor<sup>55,56</sup>

### Heart rate monitors using photoplethysmography

Heart rate monitors using plethysmography are usually designed as watches (Figure 17) or the new one version is as headband or cap (Figure 18). There are few of them in the market at this time and new products are coming in near future. Products that can be obtained in the market are: RHYTHM+ heart rate monitor by Scosche<sup>57</sup>, MIO Link, MIO Alpha<sup>58</sup>, Samsung Gear series products<sup>59</sup>, Spree Headband<sup>60</sup>, Basis Health Tracker<sup>61</sup>.

Scosche<sup>62</sup> and MIO products<sup>63</sup> were compared with ECG/chest strap solutions for heart rate measurement and found to be not worse (or even better) than the chest strap based heart rate monitors.

Main features and specifications (for most of them):

- Wireless connectivity: Bluetooth 4.0 and ANT+(RHYTMH+ and MIO Link have both); Bluetooth 2.1 for Basis Health Tracker
- Continuous heart rate monitoring
- Have dedicated apps (also have compatibility with other apps, but usually with limited functionality of various calculated parameters)
- Heart rate range:
  - o 30-220 BPM
- Working time:
  - 8-10 hours (MIO Alpha and Link)
  - Up to 8 hours (RHYTHM+)
- Prices:
  - 100 EUR for MIO Link
  - 170 EUR for MIO Alpha
  - 90 EUR for RHYTHM+
  - $\circ$   $\,$  200 EUR for Spree  $\,$

<sup>&</sup>lt;sup>55</sup> <u>http://s1.ibtimes.com/sites/www.ibtimes.com/files/styles/v2\_article\_large/public/2014/02/28/galaxy-s5-heartratesensor.JPG</u>

<sup>&</sup>lt;sup>56</sup> <u>http://static.trustedreviews.com/94/00002baa5/050a/galaxy-s5-heart-rate.jpg</u>

<sup>&</sup>lt;sup>57</sup> <u>http://www.scosche.com/rhythm-plus</u>

<sup>&</sup>lt;sup>58</sup> <u>http://www.mioglobal.com/en-uk/explore-mio-products.htm</u>

<sup>&</sup>lt;sup>59</sup> <u>http://www.samsung.com/global/microsite/gear/index.html</u>

<sup>&</sup>lt;sup>60</sup> <u>http://spreesports.com/</u>

<sup>&</sup>lt;sup>61</sup> <u>http://www.mybasis.com/</u>

<sup>&</sup>lt;sup>62</sup> http://www.scosche.com/downloads/dl/file/id/771/rhythm\_vs\_polar\_chest\_strap\_study.pdf

<sup>&</sup>lt;sup>63</sup> <u>http://www.mioglobal.com/en-uk/mio-heart-rate-technology.htm</u>



- o 150 EUR for Basis Health Tracker
- o 155 EUR for Samsung Gear Fit
- o 280 EUR for Samsung Gear 2
- o 192 EUR for Samsung Gear 2 Neo
- o 200 EUR for Samsung Gear Life





Figure 17. MIO Alpha and MIO Link heart rate monitors<sup>64</sup> (left) and Scosche RHYTHM+ heart rate monitor<sup>65</sup> (right)



Figure 18. Spree heart rate and activity tracking device<sup>66</sup> as head band (left) or cap (right)

### 2.3.1.3. Electrocardiogram (ECG)

#### AliveCor Heart Monitor

AliveCor Heart Monitor<sup>67</sup> is the attachment to the smart phone (see Figure 19 and Figure 20) enabling registration of one lead ECG between the hands (Lead I on standard ECG) and the heart rate. The device converts ECG into ultrasound signals (FM, 19 kHz, 200 Hz/mV) transmitted to the mobile device's microphone. This approach allows long battery life (up to 12 months).

The main AliveCor Heart Rate monitor features and specifications:

- Frequency response 0,5 Hz 40 Hz
- Can record ECG of 30 s (18 KB of memory space) to 10 min length
- Maximum detected heart rate 300 beats per minute
- FDA cleared and approved by clinical studies<sup>68</sup>
- Compatible smart phones: iPhone (iOS 5.0 and higher) and Android (4.0 and higher)<sup>69</sup>

<sup>&</sup>lt;sup>64</sup> <u>http://www.mioglobal.com/en-uk/explore-mio-products.htm</u>

<sup>&</sup>lt;sup>65</sup> <u>http://www.scosche.com/media/catalog/product/cache/1/image/fa2b5b80d1710c24fc26c58ffa4e7580/r/t/rthm19-angle-1000\_1.jpg</u>

<sup>66</sup> http://spreesports.com/

<sup>&</sup>lt;sup>67</sup> <u>http://www.alivecor.com/home</u>

<sup>&</sup>lt;sup>68</sup> Saxon L.A. et *al.* Ubiquitous Wireless ECG Recording: A Powerful Tool Physicians Should Embrace. Journal of Cardiovascular Electrophysiology, 2013; Vol.24: 480-483, and Lau J.K. et *al.* iPhone ECG application for community screening to detect silent atrial fibrillation: A novel technology to prevent stroke. International Journal of Cardiology, 2013; Vol 165:193-194.

<sup>69</sup> http://www.alivecor.com/compatibility





Figure 19. AliveCor Heart Monitor<sup>70</sup> (on the left: with universal attachment plate; on the right: attached to the mobile phone<sup>71</sup> (also there is option with the case for iPhone 5/5S))



Figure 20. Set up and ECG acquisition on the phone with AliveCor<sup>72</sup>

For the recording of ECG the user must launch AliveECG app and select recording. For the Lead I ECG acquisition, user holds the monitor using two hands; for the Lead II, one electrode should be placed on the left knee and the right hand should touch another; for an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle. Indicator in the app indicates contact with the skin and starts recording then contact is sufficient. Recording lasts depending on the apps settings. After the saving of ECG, user can review the recording, email, print or share a PDF report.

If the user is a health conscious individual (non-prescribed to AliveCor service), there is no possibility to review the recording (only to check the report in email if the user sent it after the recording). AliveCor also offers server for the data transfer and management, but it also offers full functionality of it **only for the prescribed users**. AliveCor Heart Rate monitor and full service are available for 199 USD in U.S.A. and for 169 GPB in U.K. and Ireland.

## Zephyr BioPatch

Zephyr BioPatch<sup>73</sup> is the device for the heart function and activity monitoring that attaches to the patient via traditional disposable ECG electrodes (see Figure 21). This device was designed for continuous monitoring of: heart rate, R-R interval, respiration rate, ECG, activity level, position and posture.

Main features and specifications of BioPatch:

- Long transmission range
- Long Battery Life
- Water Resistant up to 1m
- Can be disinfected with standard cleaning agents
- Heart Rate Range: 0 240 BPM (± 1 BPM)

<sup>&</sup>lt;sup>70</sup> <u>https://alivecorcms.s3.amazonaws.com/sites/51b0fa1d9005a1000f00292e/theme/images/um.png</u>

<sup>&</sup>lt;sup>71</sup> <u>http://cdn.medgadget.com/wp-content/uploads/2014/02/AliveCor-Heart-Monitor.jpg</u>

<sup>72</sup> http://www.alivecor.com/how-to-set-up

<sup>&</sup>lt;sup>73</sup> <u>http://zephyranywhere.com/products/biopatch/</u>



- Respiration Rate: 0 70 Breaths per Minute (± BPM)
- Position/Posture ± 180° (Lying, Vertical)
- Accelerometry: 3-Axis (± 16g)
- ECG Type: EC38 Type 3 ECG
- Battery Type: Rechargeable Li Ion
- Battery Life: 24 Hours per charge
- Water Resistance: Up to 1m (IP67)
- BioModule Dimensions: 28mm Diameter x 7mm thick
- BioModule Weight: 18 grams

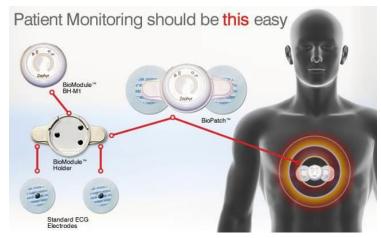


Figure 21. Zephyr BioPatch monitoring device<sup>73</sup>

Unfortunately, this device is sold as a whole system, and is available to the consumers based on prescription only. Device is integrated in ZephyrLIFE remote patient monitoring system. There are two versions of this system: ZephyrLIFE–Home<sup>74</sup> and ZephyrLIFE–Hospital<sup>75</sup>. The structures of the systems are shown in Figure 22.

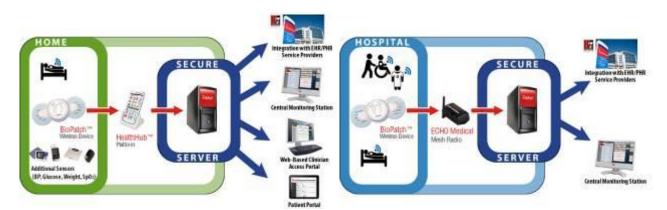


Figure 22. ZephyrLIFE–Home<sup>74</sup> (left) and ZephyrLIFE–Hospital<sup>75</sup> (right) remote patient monitoring systems

<sup>&</sup>lt;sup>74</sup> <u>http://zephyranywhere.com/healthcare/zephyrlife-home/</u>

<sup>&</sup>lt;sup>75</sup> <u>http://zephyranywhere.com/healthcare/zephyrlife-hospital/</u>



### nECG platform by Nuubo wearable medical technologies

The platform<sup>76</sup> consists of special shirt nECG SHIRT with integrated proprietary textile electrodes (BlendFix sensor), nECG MINDER wireless (Bluetooth) medical device for signal registration (position/posture, physical activity and ECG) and analysis software for visualizations and management of information.



Figure 23. nECG platform<sup>77,78</sup> by Nuubo wearable medical technologies

Main features and specifications of nECG platform:

- Textile electrode dimensions: size 45 x 45 mm, profile 1 mm, sensor diameter 30 mm  $\cdot$  sensor area 707  $\text{mm}^2$
- Fabric content: 70% Polyester; 20% Nylon; 10% Elastane
- Design: ergonomic clothes which adapt to the body assuring the best performance and ECG quality signal even at high level of physical activity
- Connectors: 2 snap connectors compatible with wireless nECG MINDER
- Communications: Bluetooth® wireless technology, v2.0 + EDR compliant, Class I (up to 200 m outdoor range)
- ECG: Single-channel, sampling rate 250 sps (12-bits), bandwidth 0.05-100 Hz
- Accelerometry: 2 GB capacity (removable micro-SD card, stores up to 22 days in continuous recording mode)
- Heart rate transmitter: Measurement range 30-240 bpm, compatible with HR monitors utilizing 5 kHz transmission technology
- Weight: 54 g (with battery)
- The analysis software nECG SUITE allows the processing of all the information registered or transmitted through the nECG MINDER. The system offers the possibility to visualize a multitude of graphics offering contextualization from the electrocardiogram signal. The software also contains reporting tools that help with diagnosis and HRV analysis.

Different clinical studies<sup>79,80</sup> and trials<sup>81</sup> have been carried out to evaluate the ECG signal quality of Nuubo's platform. The company has received CE Mark approval for the commercial sale of its wearable ECG solution. This product complies with the Medical Device Directive 93/42/EEC. The company achieved ISO 13485 and ISO 9001 certifications. Nuubo products and solutions are marketed worldwide via subsidiaries and distribution partners. Nuubo informs, that it is building a network of qualified distributors in Europe, but at this time do not offer purchase possibilities.

<sup>&</sup>lt;sup>76</sup> <u>http://www.nuubo.com/?q=en/node/165</u>

<sup>&</sup>lt;sup>77</sup> http://img0.medicalsearch.com.au//Products/Images/116656\_3.JPG

<sup>&</sup>lt;sup>78</sup> <u>http://2.bp.blogspot.com/-ZtCHVXs4QJU/TmJNmYtXeFI/AAAAAAAHV4/CXM1jLnKPqU/s1600/</u> <u>Camiseta+y+Dispositivo+baja+res+%25282%2529 thumb a.jpg</u>

<sup>&</sup>lt;sup>79</sup> <u>http://www.ncbi.nlm.nih.gov/pubmed/21925751</u>

<sup>&</sup>lt;sup>80</sup> <u>http://www.escardio.org/communities/councils/ccp/e-journal/volume10/Pages/Wearable-electronics-new-method-for-cardiac-rhythm-monitorisation.aspx#.U8VdkPmSx8E</u>

<sup>&</sup>lt;sup>81</sup> <u>http://www.elsevier.es/sites/default/files/elsevier/pdf/298/298v46nEsp.Congresoa90003331pdf001.pdf</u>



#### Shimmer ECG monitoring device

Shimmer<sup>82</sup> provides open platform for wireless wearable data acquisition from various sensors, including biomedical. Platform consists from Shimmer3 base unit and daughter boards that interface with the biomedical sensors. Using the Shimmer3 ExG module (see Figure 24) that is a configurable digital front-end, optimised for the measurement of ECG and EMG signals, ECG monitoring can be carried out<sup>83</sup>. Several research papers are published<sup>84</sup> using Shimmer platform, mostly showing application cases, not clinical studies.



Figure 24. Shimmer3 ExG Bundle<sup>85</sup>

Features and specifications of the Shimmer3 ExG module:

- Five-wire, four-lead ECG solution, measuring bipolar limb leads and user's choice of V1 V6
- Respiration demodulation from ECG data and lead-off detection capability on-chip
- Software configurable right-leg drive for common-mode interference rejection (Wilson Type Driven Ground)
- Software configurable amplifier gain
- Software configurable data rate (125...8000 SPS)
- Test signal on-chip for validation purposes
- Main microcontroller: MSP430 (24MHz)
- Wireless communication: Bluetooth Radio RN-42
- Integrated 2GB micro SD card
- 450mAh rechargeable Li-ion battery
- All Hospital-Grade 1mm Touchproof IEC/EN 60601-1 DIN42-802 jacks
- Ultra-lightweight (31 grams)
- Compact Dimensions (65 x 32 x 12 mm)
- Includes wide range of software interfaces to: Windows, Android, LabView, Matlab, Java, C#.
- Price: 540 EUR (Shimmer3 ExG Bundle, included unit and lead pack) or 1849 EUR (ExG Development Kit, included 3 ECG units, docking station, straps, etc.)

#### Omron Healthcare Model HCG-801

HeartScan is a portable compact standalone ECG recorder that the patient can carry with himself. When the patient feels the symptoms of a heart problem, he/she reaches for the HeartScan and makes a 30-second

<sup>&</sup>lt;sup>82</sup> <u>http://www.shimmersensing.com/</u>

<sup>83</sup> http://www.shimmersensing.com/images/uploads/docs/ExG - 2014 - Rev 1.2.pdf

<sup>&</sup>lt;sup>84</sup> <u>http://www.shimmersensing.com/enterprise/current-use/wearable-sensor-research-papers/</u>

<sup>&</sup>lt;sup>85</sup> <u>http://www.shimmersensing.com/assets/images/content/page\_banners/1231/exg-bundle1\_medium.gif</u>



recording of his/her heart's waveform. The ECG analysis on the device provides information on heart rate, rhythm and the ECG waveform. The single lead recording runs for 30 seconds and includes a multilevel display of deviations from the norm as well as the date and time of the recording, the heart rate and the short cut analysis. Device was tested in some clinical tests and trials<sup>86,87</sup> and showed good results comparing with traditional ECG measurement devices even in children population<sup>88</sup>.



Figure 25. Omron HeartScan<sup>89,90</sup>

Main features and specifications:

- Bipolar single channel
- The ECG analysis provides information on heart rate, rhythm and the ECG waveform
- 30 seconds measurement
- Heart rate range: 2 to 200 beats/min.
- Bandwidth: 0.05 to 40 Hz
- Sampling Rate: 125 Hz
- Enclosure ingress protection: IP20
- Memory: 5 measurements (using the unit's internal memory); 300 measurements (using the supplied SD memory card)
- Data transfer to PC could be performed by removing SD memory card and copying data files
- Data files can be opened using freely downloadable software "ECG Viewer"<sup>91</sup>, files are with "\*.ecg" (hopefully kind of SCP-ECG format)
- Power Supply: 2 LR03 (AAA) batteries; battery life: approximately 400 measurements with alkaline batteries (when measurements are taken once a day at room temperature (22 °C))
- Weight: approximately 130g (including batteries)
- Dimensions: 121 mm (W) × 67 mm (H) × 24 mm (D)
- Price 375 EUR

## Beurer ME80 ECG recording device

Beurer ME80<sup>92</sup> is one button operated ECG recording device (see Figure 26, top) that requires approx. 30 seconds to take the cardiogram measurement. The device automatically runs an analysis based on the measurement data and delivers the corresponding results.

<sup>&</sup>lt;sup>86</sup> <u>http://europace.oxfordjournals.org/content/11/10/1362.full</u>

<sup>&</sup>lt;sup>87</sup> http://europace.oxfordjournals.org/content/15/5/657.full

<sup>&</sup>lt;sup>88</sup> <u>http://europace.oxfordjournals.org/content/13/9/1335.full</u>

<sup>&</sup>lt;sup>89</sup> <u>http://www.vicareydavidson.com/media/catalog/product/cache/1/image/9df78eab33525d08d6e5fb8d27136e95/o/m/omron\_ecg\_heartscan\_hcg\_side.jpg</u>

<sup>&</sup>lt;sup>90</sup> http://www.omron-healthcare.com/cache/images/ffc2384b85cef16b6c49678ea68baba8\_normal.jpg

<sup>&</sup>lt;sup>91</sup> <u>http://www.ecg-soft.com/ecgviewer/ecgviewer.htm</u>

<sup>&</sup>lt;sup>92</sup> <u>http://www.beurer.com/web/en/products/mobile\_ecg/mbile\_ecg/ME-80</u>



Maine features and specifications:

- System of measurement of single-channel ECG in freely selectable frontal positions
- ECG signal referenced to ground (earth)
- Bandwidth 0.05 to 40 Hz
- Sample rate 256 Hz
- Measurement range for heart rate: 5 to 199 beats per min.
- Power supply: integrated, rechargeable lithium battery
- Battery capacity: over 1,000 measurements on a full charge
- ME80 allows a maximum of 99 measurement data records to be stored on the device itself.
- Saving any further measurement data records will overwrite old records.
- Uses proprietary "Beurer ECG Manager" software for downloading ECG data, configuring ECG device, saving measurements in chronological order, independently monitoring health, displaying ECG waveforms as reference data for medical specialists, printing the ECG as a useful means of providing important information to your doctor
- Weight 40 g
- Price: 175 EUR

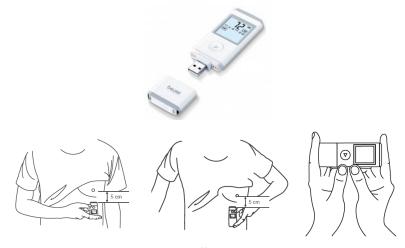


Figure 26. Beurer ME80 ECG recording device<sup>93</sup> (top) and different ways for recording<sup>94</sup> (bottom)

Measurements can be carried in three different ways: "right index finger-chest", "left index finger-chest", "left hand-right hand" (see Figure 26 bottom).

### Beijing Choice Electronic Tech Co., Ltd devices

China based company Beijing Choice Electronic Tech Co., Ltd (marketing names ChoiceMMed, HeartCheck<sup>95</sup> or Heart Observer) offers few ECG recorders<sup>96</sup> (see Figure 27, Figure 28, Figure 29).

<sup>&</sup>lt;sup>93</sup> <u>http://www.tomsona.lt/media/catalog/product/cache/1/image/700x/9df78eab33525d08d6e5fb8d27136e95</u> /m/e/me80-open.jpg

<sup>&</sup>lt;sup>94</sup> http://sklep.poradnia.pl/images/beurer/ME%2080%20POMIAR.JPG

<sup>&</sup>lt;sup>95</sup> <u>http://www.theheartcheck.com/</u>

<sup>&</sup>lt;sup>96</sup> <u>http://www.choicemmed.com/list.aspx?id=23</u>





Figure 27. MD100E1 ECG recorder<sup>97,98</sup>



Figure 28. MD100B1 ECG recorder<sup>99</sup>



Figure 29. ECG PEN<sup>100</sup>

<sup>&</sup>lt;sup>97</sup> <u>http://cdn2.bigcommerce.com/server1600/6aedc/products/159/images/381/MD100E\_04140.1339814</u> 044.1280.1280.JPG?c=2

<sup>&</sup>lt;sup>98</sup> <u>http://ecx.images-amazon.com/images/I/61V4ynuHp0L. SY679 .jpg</u>

<sup>&</sup>lt;sup>99</sup> <u>http://ecx.images-amazon.com/images/I/71olOiInIIL\_SL1500\_.jpg</u>

<sup>&</sup>lt;sup>100</sup> <u>http://www.theheartcheck.com/images/pen-device-banner-VIDEO\_02.jpg</u>





Figure 30. MD100A12 ECG recorder<sup>101</sup>

Three of them (MDA100A12, MDA100B1, MDA100E1) can be used in two ways for ECG recording: 1) with their on-device electrodes by touching them or placing to body and 2) using ECG cable attached to the ordinary electrodes. ECG PEN is used only with electrodes on the device. The functionality of these devices is the same as Beurer ME80 and Omron HCG801.

Specifications of devices:

- Recording length: 30s
- Signal bandwidth 0,5-75 Hz (1 Hz-40 Hz for ECG PEN)
- Sampling rate: 250 Hz
- Battery life: 500 measurements
- Records are stored in internal memory or SD card (MD100E allows continued recording then using SD card) and can be viewed using proprietary software on PC
- Price: 160 EUR (MD100A12), MD100E (220 EUR), 195 EUR (MD100B), 160 EUR (EKG PEN)

# Zenicor-EKG recorder

Zenicor-EKG recorder<sup>102</sup> (by Zenicor Medical Systems AB, Sweden) is clinically tested (used in several clinical studies in Sweden as a tool for arrhythmia and AF follow up outside the hospital – see references in <u>http://www.zenicor.com/zenicor\_ekg</u>) dry thumb electrodes ECG recording device.



Figure 31. Zenicor-EKG device<sup>103</sup>

Features and specifications:

- Built-in GSM/GPRS modem
- 10, 20 or 30 seconds, limb lead I registration by attaching two thumbs on the device
- Possibility for patient to indicate symptom for the registration

<sup>&</sup>lt;sup>101</sup> <u>http://www.win-health.com/sites/default/files/wpro\_shared/images/heart-observer-ecg/md-100a-using-l.jpg</u>

<sup>&</sup>lt;sup>102</sup> <u>http://www.zenicor.com/zenicor\_ekg</u>

<sup>&</sup>lt;sup>103</sup> <u>http://www.boehm-elektromedizin-gmbh.de</u>



- Built-in mobile phone enables user initiated automatic sending of the ECG to the Internet connected ECG database with patients integrity secured. The ECG database can be reached by the care provider from any Internet connected computer. No installation or specific software is required
- ECG is presented to the care giver in easy to read menus, with built-in tools for arrhythmia diagnostics
- Memory for up to 200 ECG readings
- Dimensions: 145 x 65 x 25 mm
- Weight: 135 g (excl. batteries)
- Power supply: Three 1.5V AA batteries (lasts for about 500 readings and sendings)

#### eMotion ECG devices

eMotion ECG Mobile<sup>104</sup> (see Figure 32) is a remote electrocardiography monitoring system developed by Mega Electronics Ltd, Finland. The ECG data is being transmitted from the ECG sensor to mobile phone via Bluetooth. Phone forwards the data over mobile network to server, which stores the data. The data can be reviewed in two ways: with a web browser for analysing purposes or with a real time monitoring view on a computer. From the web browser a specialist can investigate and analyse thoroughly the stored ECG data.



Figure 32. eMotion ECG device<sup>105</sup> and system<sup>106</sup>

Main features and specifications of the sensor:

- Sampling rate: up to 1000 Hz
- Functioning range: 100 m
- Accuracy: 1 ms
- Battery life: Bluetooth online up to 27 h (with 100 Hz)
- Recharging time: ca. 1 hour
- Weight: 16g
- Dimensions: 35mm x 35mm x 15mm
- Price: 890 EUR

eMotion Faros device family<sup>107</sup> (Figure 33) is a tool for monitoring ECG, stress, recovery and general wellbeing. eMotion Faros early detection data helps preventing stress related issues at the workplace. Optimal mental and physical balance is proven to improve productivity and overall enjoyment of the working environment. Lightweight, small and easy to use eMotion Faros Series leads the way to well-being. All

<sup>&</sup>lt;sup>104</sup> <u>http://www.megaemg.com/products/emotion-ecg/</u>

<sup>&</sup>lt;sup>105</sup> <u>http://shop.megaemg.com/tuotekuvat/450x450/eMotion-ECG\_copy1.jpg</u>

<sup>&</sup>lt;sup>106</sup> <u>http://archivetips.com/wordpress/wp-content/uploads/2014/02/75b35ebed5fcb5e9845c87f3a3243204.jpg</u> <u>?682336</u>

<sup>&</sup>lt;sup>107</sup> <u>http://www.megaemg.com/products/faros/</u>



eMotion Faros devices and mounting options offer the latest, most innovative technology on heart rate variability and physical activity monitoring.



Figure 33. eMotion FAROS device family<sup>107</sup>

eMotion Faros 90° main features and specifications:

- Heart rate variability
- 3D acceleration (physical activity tracking)
- ECG offline recording (holtering)
- Memory capacity up to 2 months measurement
- Rechargeable battery
- USB download
- ECG sampling rate up to 250 Hz
- Weight 13g
- Price: 399 EUR

eMotion Faros 180° main features and specifications:

- Heart rate variability
- 3D acceleration (physical activity tracking)
- ECG online (Bluetooth) / offline (holtering)
- 1 GB memory
- Rechargeable battery
- Bluetooth
- USB download
- ECG Sampling rate up to 1000 Hz
- Weight 13g
- Price: 494 EUR

eMotion Faros 360° main features and specifications:

- Heart rate variability
- 3D acceleration (physical activity tracking)
- ECG online (Bluetooth) / offline (data logging)



- Temperature
- Breathing
- Max 16 BG memory
- 3 channel ECG
- Rechargeable battery
- Bluetooth
- USB download
- Sampling rate 1000 Hz (1000 samples per second allows accurate description of heart function)
- Weight 13g
- Price: 990 EUR

Easy to use eMotion Lab software for data handling and reviewing is included with all eMotion Faros sensors. A more comprehensive HRV Scanner software for HRV data analysis can be purchased as an option. HRV Scanner allows you to visually follow up, interpret and create reports of stress and well-being through its user-friendly interface.

## CamNtech Limited ECG recording devices

CamNtech Limited produces two wearable devices for ECG waveforms recording: Actiwave Cardio<sup>108</sup> (Figure 34) and Actiheart<sup>109</sup>. The Actiwave Cardio is a waterproof ultra-miniature single channel ECG waveform recorder. It consists of two electrodes connected by a short lead, which simply clip onto two standard ECG pads worn on the chest. It also contains a tri-axial accelerometer, the signal from which allows the user to determine resting body position. For a single channel 24 hour recording the Actiwave Cardio gives excellent wearability. The very small size allows for continuous monitoring in a wide range of patients and applications. For data download Actiwave Cardio should be removed from the electrodes and placed on a docking station connected to a PC. The Actiwave Control Software transfers data from the recorder to the PC via the dock and USB cable. Actiwave Control Software software also is used for the setup of the Actiwave Cardio device. Actiwave data is stored on the PC in European Data Format (EDF+) files. The user may view and analyse the files using several popular third-party software packages, including some public-domain software.

Main features and specifications of Actiwave Cardio:

- Record a full single channel ECG waveform for up to 31 hours
- Simultaneously record 3-axes of acceleration
- Combine heart rate and activity to calculate energy expenditure
- Use acceleration data to record body position
- The sampling frequency can be varied for both the ECG and accelerometry capture, and up to 10 bit resolution is available.
- The recording time specified above refers to 128Hz ECG recording alongside 32Hz acceleration, with 8 bits recorded.
- Compact and lightweight
- Rechargeable
- Price: 1010 EUR (Cardio unit) + 440 EUR (CardioDock) + 505 EUR (Cardio Analysis Software)
- Actiwave Cardio is widely used in scientific studies<sup>110</sup>.

<sup>&</sup>lt;sup>108</sup> <u>http://www.camntech.com/products/actiwave-cardio/actiwave-cardio-overview</u>

<sup>&</sup>lt;sup>109</sup> <u>http://www.camntech.com/products/actiheart/actiheart-overview</u>

<sup>&</sup>lt;sup>110</sup> <u>http://www.camntech.com/products/actiwave-cardio/cardio-bibliography</u>





Figure 34. Actiwave Cardio<sup>111</sup> (top left) and Actiheart<sup>112</sup> (top right) and application cases<sup>113</sup>

The Actiheart is a compact, chest-worn monitoring device that records heart rate, Inter-Beat-Interval (IBI), and physical activity. It is designed for capturing HRV data and for calculating and measuring Activity Energy Expenditure.

Main features and specifications:

- Record Heart rate and activity for up to 21 days
- Record IBI for up to 440,000 beats (3.5 days @ 76bpm)
- Compact and lightweight: less than 10 grams
- Clips onto two ECG electrodes worn on the chest
- Can also be worn on a belt, similar to a Polar wearlink belt
- Waterproof design
- Available as a paediatric monitor
- Price: 1200 EUR (Actiheart unit) + 465 EUR (Actiheart reader/charger) + 1200 EUR (Actiheart software)

The Actiheart has two clips, which attach directly to standard ECG electrodes. Usually one electrode is adhered at V1 or V2 (fourth intercostal) and the second electrode is placed approximately 10 cm away on the left side at V4 or V5, although this placement can be adjusted to be comfortable for the subject. The number of R-waves detected is recorded in 15, 30, or 60 second epochs. Simultaneously, an internal accelerometer senses the frequency and intensity of the subject's torso movements. The Actiheart is ideal for use in both short and long term monitoring situations.

Actiwave Cardio offers short period waveform recording at greater resolution than the Actiheart, alongside the three axis accelerometry data. Actiheart's has longer-term recording and lower energy expenditure. Both devices are capable of capturing data for Heart Rate Variability (HRV) analysis.

Actiheart is widely used in scientific studies<sup>114</sup> too.

<sup>&</sup>lt;sup>111</sup> <u>http://vivonoetics.com/wp-content/uploads/2012/02/Cardio\_cutout\_275.jpg</u>

<sup>&</sup>lt;sup>112</sup> <u>http://www.bmedical.com.au/img/products/product\_15.jpg</u>

<sup>&</sup>lt;sup>113</sup> http://www.bmedical.com.au/shop/activity-heat-research/actiheart.htm

<sup>&</sup>lt;sup>114</sup> http://www.camntech.com/products/actiheart/bibliography



#### ePatch ECG recorder

The ePatch®<sup>115</sup> made by DELTA Dansk Elektronik is a small, discreet body-worn patch sensor (Figure 35) that adheres to the skin. The ePatch® continuously records, stores and wirelessly transmits the following physiological data: ECG, heart rate, activity and motion. Device has no cables and can be worn for many days. ePatch® electrode should be clicked on the ePatch® sensor, and placed on the sternum. Then the ePatch® ECG recorder automatically starts recording until you remove it. No set-up and no configuration are needed. After end of recording ePatch® ECG recorder should be plugged into the PC via the USB connection. The ECG recording will be available as a file. Also can be modifications of ePatch with wireless connectivity.



Figure 35. ePatch ECG recorder<sup>116</sup>

Main features and specifications:

- 1 or 2 ECG channels with 128, 256, 512, 1024 samples/sec
- Convenient internal Flash Data Storage 2GB
- No installation of any software
- Weight 15 g
- Dimensions 48 x 40 x 8.8 mm
- Battery type Lithium Ion polymer (built in)
- Connections microUSB
- Record duration Up to 72 hours
- Sampling rate 512 samples/sec
- Frequency response 0.67 40 Hz
- Resolution 12 bit
- Water resistance IP 22 (short showers)
- Output format Proprietary EFS format
- Recording stop: after set time or upon disassembly
- Embedded data compression Yes/No (options)
- Embedded data encryption Yes/No (options)
- Embedded pulse trend Yes/No (options)
- Embedded HRV algorithm (and raw ECG) Yes/No (options)
- RF Zigbee (BLE,Wifi, 833/900) (options)
- Accelerometer 3-axial

<sup>&</sup>lt;sup>115</sup> <u>http://www.madebydelta.com/imported/images/DELTA\_Web/documents/ME/ePatch/ePatch\_specifications\_low2.pdf</u>



DELTA offers ePatch® technology platform for customers for developing and marketing own specific patch based solution under own brand.

#### 2.3.1.4. Blood oxygenation (SpO2)

Blood oxygenation is measured by pulse oximeters. In the market we can found plenty of them, but for CARRE application cases we will focus on the ones with less obtrusive usage. The preferences are: newest technologies of wireless connectivity, open data, battery life, and comfort for patients.

#### Nonin pulse oximeters for blood oxygenation measurements

Onyx II 9560 finger pulse oximeter<sup>116</sup> (Figure 36, left) has Bluetooth 2.0 communication and provides a secure wireless connection for vital information exchange. Extremely versatile, it easily connects to communication devices (smart phones, PCs, etc.). Device is designed to meet the requirements of the emerging Bluetooth Health Device Profile (HDP), IEEE 11073 and Continua standards. This pulse oximeter ensures ultimate versatility by allowing patients to take readings when a wireless connection is not possible. When the patient returns into range, The Onyx II 9560 automatically transmits the time-stamped data. The Onyx II 9560's memory storage provides a minimum of 20 single point measurements. SmartPoint Technology used in this device provides a fast and accurate snapshot of the patient's SpO2 and pulse rate and eliminates the guesswork of determining which oximetry values to use for analysis. The SmartPoint algorithm automatically determines when a high quality measurement is ready to be wirelessly transmitted and each measurement includes an indicator of quality.

Main features and specifications:

- Oxygen Saturation Range (SpO2): 0 to 100%
- Pulse Rate Range: 18 to 321 beats per minute (BPM)
- SpO2 Accuracy (Arms) 70-100%: Oxygen Saturation Accuracy ± 2 digits
- Pulse Rate Accuracy (Arms) (20-250 BPM): ± 3 digits
- Internal Power Battery: two 1.5 volt AAA batteries
- Operating Life: 600 spot-checks (30 secs/spot-check) in a 6 month period.
- Weight 63 grams with batteries installed
- OEM Development Kit containing the oximeters HDP and SPP communication profiles and demonstration software
- Price: 330 EUR



Figure 36. Onyx II 9560 finger pulse oximeter<sup>117</sup> (left); Nonin 3150 Wrist-worn pulse oximeter<sup>118</sup> (center), Nonin 3230 Bluetooth Smart pulse oximeter<sup>119</sup>

<sup>&</sup>lt;sup>116</sup> <u>http://www.nonin.com/PulseOximetry/Finger/Onyx9560</u>

<sup>&</sup>lt;sup>117</sup> http://nonin.com/documents/9560%20Brochure.pdf

<sup>&</sup>lt;sup>118</sup> <u>http://www.aeromedixrx.com/images/P/3150wrist.jpeg</u>



WristOx<sub>2</sub> model 3150 wrist-worn wireless pulse oximeter<sup>120</sup> (Figure 36, center) provides highly accurate oxygen saturation and pulse rate readings in the widest range of patients and settings. From the hospital to the home, the WristOx2<sup>TM</sup> is ideal for applications including cardio-ambulatory monitoring, remote wireless monitoring and overnight studies. It is simple and easy to use, and data can be downloaded via a USB cable or wirelessly with Bluetooth 2.0 technology, providing patients with increased independence during continuous monitoring applications.

Main features and specifications:

- Oxygen Saturation Range (SpO2): 0 to 100%
- Pulse Rate Range: 18 to 321 beats per minute (BPM)
- SpO2 Accuracy (Arms) 70-100%: Oxygen Saturation Accuracy ± 2 digits
- Pulse Rate Accuracy (Arms) (20-250 BPM): ± 3 digits
- Internal Power Battery: two 1.5 volt AAA batteries
- Battery Life:
  - Operating without Bluetooth: 48 Hours minimum
  - Operating with Bluetooth: 24 Hours minimum
- Memory capacity:
  - Up to 1080 hours@4 sec. data storage rate
  - Up to 540 hours @ 2 sec. data storage rate
  - Up to 270 hours @ 1 sec. data storage rate
- OEM Development Kit containing the oximeters HDP and SPP communication profiles and demonstration software
- Price: 800 EUR

The third device offered from Nonin is Model 3230 finger pulse oximeter<sup>121</sup> (Figure 36, right) OEM solution with Bluetooth Smart wireless technology, which provides a simplified pairing for vital information exchange over a secure wireless connection. With Bluetooth® Smart wireless technology, Nonin's clinically proven accuracy provides peace of mind in knowing you are getting precise readings.

Main features and specification:

- Oxygen Saturation Range (SpO2): 0 to 100%
- Pulse Rate Range: 18 to 321 beats per minute (BPM)
- SpO2 Accuracy (Arms) 70-100%: Oxygen Saturation Accuracy ± 2 digits
- Pulse Rate Accuracy (Arms) (20-250 BPM): ± 3 digits
- Internal Power Battery: two 1.5 volt AAA batteries
- Operating Life: 2200 spot-checks (25 secs/spot-check).
- Weight 63 grams with batteries installed
- OEM development Kit
- Price: 220 EUR

<sup>&</sup>lt;sup>119</sup> <u>http://www.nonin.com/\_images/products/LargImages/Nonin3230iPad.jpg</u>

<sup>&</sup>lt;sup>120</sup> <u>http://www.nonin.com/PulseOximetry/Wireless/WristOx2-Model-3150</u>

<sup>&</sup>lt;sup>121</sup> <u>http://www.nonin.com/OEMSolutions/Nonin\_3230\_Bluetooth\_SMART</u>



#### iHealth Wireless Pulse Oximeter

The Wireless Pulse Oximeter by iHealth is a way to spot-check blood oxygen saturation (SpO2) and pulse rate (BPM)<sup>122</sup>. This lightweight and portable device (Figure 37) takes fast, non-invasive measurements at the fingertip. SpO2 and BPM readings can be tracked and viewed directly on the device's display and in the iHealth SpO2 app during sports training or other recreational activities.

Main features and specifications:

- Wireless connectivity: Bluetooth 4.0 BLE
- SpO2 measuring range: 70-99%
- SpO2 accuracy: 70-99%,±2%; <70%, no definition
- Pulse rate measuring range: 30-250bpm
- Pulse rate accuracy: ±2bpm or ±2% larger one
- Device compatibility: iOS 5.0 or higher
- Free iHealth MyVitals mobile app. iHealth Labs application automatically transfers data to the cloud enabled service https://cloud.ihealthlabs.com. Cloud service has API: http://developer.ihealthlabs.com/index.htm Cloud service has API: http://developer.ihealthlabs.com/index.htm
- Price: 80 EUR



Figure 37. iHealth Wireless Pulse Oximeter<sup>123</sup>

## Withings Pulse O<sub>2</sub>

Pulse  $O_2$  has the blood oxygenation sensor for the spot-check measurements and is activity tracker: captures steps, distance walked, elevation climbed and calories burned (Figure 38).



Figure 38. Withings Pulse O<sub>2</sub><sup>124</sup>

Main features and specifications:

<sup>&</sup>lt;sup>122</sup> <u>http://www.ihealthlabs.eu/health-and-fitness-products-wireless-wireless-pulse-oximeter\_80.htm</u>

<sup>&</sup>lt;sup>123</sup> http://www.ihealthlabs.com:8055/images/products/pro80\_1.jpg

<sup>&</sup>lt;sup>124</sup> <u>http://www.01net.com/images/produit/full/withings-pulse-o2-3.jpg</u>



- Wireless connectivity: Bluetooth 4.0 (compatible with Bluetooth 2.0)
- Support for iOS 6.0 or higher and Android 2.3.3 or higher
- Withings app. Data storage in Withings HealthCloud. Also compatible with some others apps (TicTrac, Carepass, GenieMD, ovia). Has API: http://oauth.withings.com/api
- Has API: http://oauth.withings.com/api
- Battery: Lithium-ion, 2 week between charges
- Price: 120 EUR

#### Tinkė from Zensorium

Tinkė from Zensorium measures heart rate, respiratory rate, blood oxygen saturation level & heart rate variability from the touch of the finger (Figure 39). Comparison of Tinkė measurements results to Masimo Pulse oximeter (Rad-5)<sup>125</sup> showed good agreement.



Figure 39. Tinke photoplethysmography device<sup>126</sup>

- Wireless connectivity: Bluetooth 4.0
- SpO2 range: 90 100%
- Heart rate: 40 120 bpm
- Respiratory rate: 8 20 bpm
- Compatibility: Android
- Accuracy:
  - Heart rate: +/- 2 bpm
  - Respiratory rate: +/- 2 bpm
  - Blood oxygen saturation: +/- 1% in the 96 100 % range; +/- 2% in the range below 96%
- Battery: Lithium-ion, Approximately 120 spot checks, 30 days typical.
- Price: 130 EUR

## 2.3.2. Summary

Tables below (Tables 2-5) summarize main features and specifications of devices for cardiovascular state monitoring for everyday use by the patients. The main criteria for the analysis were: highest quality of measured parameter, newest connectivity technologies (Bluetooth v4.0), additional measurements that could enable to use device for measuring another observables, programming level connectivity for data transfer/gathering, price level. In tables parameters of these criteria were analysed and marked by the

<sup>&</sup>lt;sup>125</sup> <u>http://zensorium.com/tinke/docs/Comparison\_of\_Tinke\_(lightning)\_to\_Masimo\_(Rad\_5).pdf</u>

<sup>&</sup>lt;sup>126</sup> <u>http://www.zensorium.com/tinke/</u>



colours: **green** colour means "excellent", **yellow** colour means "satisfactory" and no colour means "neutral". Then the two devices were chosen in each category. The best one was marked by green colour, the second one – by yellow colour.

Summarising, for the monitoring of blood pressure is recommended: Medisana BU 550 connect or BU 575 connect Blood Pressure Monitors or Withings Blood Pressure Monitor.

For the monitoring of heart rate is recommended: **HxM Smart heart rate monitor (Zephyr)** or **Samsung Gear Fit** or **Samsung Gear 2 Neo** devices. The first one uses chest strap and the others use photopletysmography-based sensors on the wrist. Chest strap usually gives better results than the photopletysmography-based sensors.

For ECG recording at home could be recommended **eMotion Faros 180°** or **eMotion Faros 90°** by Mega Electronics Ltd. These devices also have accelerometer, so they could be used as activity trackers also. There is not clear question about the data transferability from these devices to the CARRE database at this moment.

For blood oxygenation measurement recommended devices are: Withings Pulse O2 – for spot-check measurements) and WristOx2 model 3150 (Nonin) – for continuous measurements of blood oxygenation.

	Table 2. Blood pressure measurement devices														
No.	Device	Measured parameters	Connectivity	Additional measurements	Compatibility	Comments on API, data gathering	Price, EUR	Other							
1	QardioArm (Qardio Inc.)	40~250 mmHg for blood pressure 40~200 beats/minute for pulse	Bluetooth 4.0	Irregular heart beat	iOS 7.0 or later	Qardio app for iOS. Allows sharing information of measurements	109	Clinically validated Light, compact and portable (140x38x68 mm, 310 g)							
2	Model BM 75 (Beurer)	systolic 30–280 mmHg	NFC, USB	Arrhythmia detection		Free Beurer software "Health Manager" what have connection with Microsoft HealthVault	90	Medical product							
3	Model BM 85 (Beurer)	diastolic 30–280 mmHg pulse 40–199	Bluetooth 4.0		iOS and Android 4.3 and up		105	Resting indicator							
4	Model BM 90 (Beurer)	beats per minute	short range RF 868MHz communication to the wireless box with wired LAN connection (wireless box connects directly to web service)				120								
5	iHealth Wireless Blood Pressure Wrist Monitor BP7	Systolic blood pressure: 60-260 mmHg Diastolic blood pressure: 40-199 mmHg Pressure	Bluetooth V3.0+EDR Class 2 SPP		iOS, Android	Free iHealth MyVitals mobile app. Available for iPhone, iPad or iPod touch and for Android. iHealth Labs application automatically transfers data to the cloud enabled service <u>https://cloud.ihealthlabs.com</u> . Cloud service has API: <u>http://developer.ihealthlabs.com/index.htm</u>	80	Measure on the Wrist Size: 72mm × 74mm × 17.6mm), Weight: 105g							
6	iHealth Wireless Blood Pressure Monitor BP5	accuracy: ±3mmHg Pulse rate range: 40 -180 beats/min,					100	Weight: 135 g (excluding cuff)							
7	iHealth Blood Pressure Dock	accuracy: ±5% Approved by ESH, EC medical, FDA, AFSSAPS	Docking station for Apple smart devices		iOS		71	Weight: 215 g (excluding cuff)							
8	Withings Blood Pressure Monitor	Pressure Measurement range: 0 to 285 mmHg, accuracy: ±3 mmHg or 2% of reading Heart rate measurement	Bluetooth 2.0 and BLE connectivity		iOS 6 or higher, Android 4.0 or higher	Withings app for iOS or Android. Data storage in Withings HealthCloud. Has API: <u>http://oauth.withings.com/api</u>	130	Weight: 600 g. (without batteries)							

		range: from 40 to 180 beats per minute, accuracy: 5% of reading Compliant with European medical device regulations and has received clearance from the FDA						
9	CardioCompact (Medisana)	Blood pressure: 40-260 mmHg Pulse: 40-180 bpm	USB	Arrhythmia indicator	iOS, Android 4.0 or higher, Windows	VitaDock+ app. Transfer of measurements results to the cloud VitaDock Online <u>https://cloud.vitadock.com/</u> . Cloud has API: https://github.com/Medisana/vitadock-api/wiki	45	Weight: 196 g
10	MTX (Medisana)	Blood pressure:					85	
11	CardioDock 2 (Medisana)	30-280 mmHg Pulse: 40-200 bpm The approval	Docking station for Apple smart devices				130 (25)	
12	CardioDock (Medisana)	according to the Medical Device Directive					130	
13	BW 300 connect Wrist (Medisana)		Bluetooth 4.0	Arrhythmia indicator			80	Weight: 150 g
14	BU 550 connect (Medisana)						90	Weight: 350 g
15	BU 575 connect (Medisana)						100	

	1																		
No.	Device	Measured parameters	Connectivity	Additional measurements	Compatibility	Comments on API, data gathering	Price, EUR	Other											
1	eMotion HRV	Continuous heart rate for HRV analysis	USB	3D acceleration (option)		eMotion LAB software is used for downloading, viewing and easy exporting of HRV data. eMotion HRV data can also be analysed with other software: Kubios HRV (freeware), Firstbeat SPORTS, Firstbeat HEALTH.	587	Uses disposable electrodes 96 hours/charge 5 days HRV data storage											
2	BioHarness 3 Model BH3 (Zephyr)	Continuous heart rate: 25-240 bpm R-R interval HR variability	Bluetooth	Breathing rate: 4- 70 bpm Acc.: ±16g posture, activity level, peak acceleration, speed & distance with GPS (optional)	Android, Windows	Widely used in research studies (BioHarness). All three modules have free software development tools for Android (BioHarness and HxM BT/Smart) and iOS (HxM Smart): <u>http://zephyranywhere.com/zephyr-labs/</u>	594	Chest strap based 26 hours/charge											
3	HxM Smart heart rate monitor (Zephyr)		Bluetooth Smart (BLE)	Stress Level Activity Level Peak Accel. Calories	iOS, Android 4.3		70	Chest strap based 150 hours battery life											
4	HxM BT heart rate monitor (Zephyr)		Bluetooth v2.0 SPP	Speed and distance (algorithm derived)	Android, Windows Phone		100	Chest strap based 26 hours/charge											
5	Polar H6	Continuous heart rate	Bluetooth Smart		iPhone 4s and later and Android 4.3 and later	Is compatible with Bluetooth® smart ready devices that support heart rate service.	60	Chest strap based Battery lifetime 300h											
6	Polar H7	Continuous heart rate Have been reported as good device for assessing heart rate variability comparing with HRV obtained with reference ECG	Bluetooth Smart, GymLink (5 kHz)				70	Chest strap based Battery lifetime 200h											
7	Armour39 (Under Armour)	Continuous heart rate (without averaging) Have been reported as good device for assessing heart rate variability comparing with HRV obtained	Bluetooth Smart	Calories, Real- time intensity, WILLpower™	iPhone 4s and later and Android 4.3 and later	Have dedicated apps (also have compatibility with other apps, but usually with limited functionality of various calculated parameters)	110	Chest strap based											

		with reference ECG						
8	Tickr (Wahoo Fitness)	Continuous heart rate	Bluetooth Smart and ANT+		iPhone 4s and later and Android 4.3 and later		60	
9	Tickr Run (Wahoo Fitness)			Accelerometer for running smoothness assessment			80	
10	Heart Rate Combo Monitor by Runtastic	Continuous heart Rate	Bluetooth Smart, GymLink (5 kHz)				70	
11	Jarv Premium Heart Rate Monitor (by Jarv Mobile)	Continuous heart rate	Bluetooth 4.0				90	
12	HRM BTLE (by Adidas)	Continuous heart rate	Bluetooth 4.0				61	Chest strap based
13	X_CELL (by Adidas)			Includes accelerometer			54	
14	RHYTMH+ (by Scosche)	Continuous heart rate: 30-220 bpm Were compared with ECG/chest strap solutions for heart rate measurement and	Bluetooth 4.0 and ANT+	Calories burned, distance, speed, pace and more	Works with All Bluetooth Smart™ and ANT+ enabled devices and equipment		90	Plethysmography based Arm band Up to 8 hours on battery
15	MIO Link (by MIO)	found to be not worse (or even better) than the chest strap based heart rate monitors			iPhone 4s and later and Android 4.3 and later		100	Plethysmography based Wrist band 8-10 hours on battery
16	MIO Aplha		Bluetooth 4.0				170	Plethysmography based Wrist band-clock 8-10 hours on battery
17	Spree Headband	Continuous heart rate	Bluetooth 4.0	Body temperature, calories burned,	iPhone 4s and later and Android 4.3 and later	Is compatible with a number of popular third party apps written for iOS and Android including Runtastic, MapMyRun, Runkeeper	200	Plethysmography based <mark>Head band</mark>

				distance, speed, time		and many others.		Up to 8 hours
18	Basis Health Tracker	Heart rate	Bluetooth 2.1	3-axis accelerometer for movements and sleep tracking; Perspiration monitor for sweet monitoring; skin temperature	iOS and Android	Will be API functions	150	Plethysmography based Wrist band-clock 4 day/charge
19	Samsung Gear Fit	Heart rate	Bluetooth 4.0 LE	Accelerometer, Gyroscope	Android 4.3 or higher	Compatible with Samsung Galaxy smart devices	155	Plethysmography based
20	Samsung Gear 2			2-3 days/charge			280	Wrist band-clock
21	Samsung Gear 2 Neo						192	
22	Samsung Gear Live			Compass, Accelerometer, Gyroscope 1 day/charge			200	

				Table 4. EC	G recording de	vices		
No.	Device	Measured parameters	Connectivity	Additional measurements	Compatibility	Comments on API, data gathering	Price, EUR	Other
1	AliveCor Heart Monitor	30 s to 10 min ECG record FDA cleared and approved by clinical studies	Ultrasound based signal transfer to smart phone microphone		iPhone (iOS 5.0 and higher) and Android (4.0 and higher)	If the user is a health conscious individual (non-prescribed to AliveCor service), there is no possibility to review the recording (only to check the report in email if the user sent it after the recording). AliveCor also offers server for the data transfer and management, but it also offers full functionality of it only for the prescribed users. Recently AliveCor Heart Rate monitor (and full service) is available U.S.A. and in U.K. and Ireland	214 EUR	On-device electrodes. Attachment to the smart phone
2	BioPatch (by Zephyr)	Continuous single lead ECG	Bluetooth	Respiration rate, position/posture, accelerometry		Device is sold as a whole system, and is available to the consumers based on prescription only. Device is integrated in ZephyrLIFE remote patient monitoring system.	-	Attaches to the disposable ECG electrodes 24 hours/charge
3	nECG MINDER (by Nuubo)	Continuous single lead ECG (0,05-100 Hz, 250 sps, 12 bit)) Clinically tested product	Bluetooth v2.0	Heart rate (5 kHz transmission), accelerometer		Nuubo products and solutions are marketed worldwide via subsidiaries and distribution partners. Nuubo informs, that is building a network of qualified distributors in Europe, but at this time do not offer purchase possibilities.	-	Textile electrodes (t-shirt) SD card
4	Shimmer3 ExG (by Schimmer)	Five-wire, four-lead ECG solution, measuring bipolar limb leads and user's choice of V1 - V6	Bluetooth			Includes wide range of software interfaces to: Windows, Android, LabView, Matlab, Java, C#	540 EUR	Traditional leads and electrodes, SD card
5	Model HCG- 801 (Omron Healthcare)	One channel ECG, 30 seconds recording 0,05-40 Hz bandwidth, sampling 125 Hz Device was tested in some clinical tests and trials	Data transfer using removable SD card			Data files can be opened using freely downloadable software "ECG Viewer", files are with "*.ecg" (hopefully kind of SCP-ECG format)	375	On-device electrodes 300 records 400 meas./charge
6	Beurer ME80 ECG	One channel ECG, 30 seconds recording 0,05-40 Hz bandwidth, sampling 256 Hz	USB			Uses proprietary "Beurer ECG Manager" software for downloading ECG data, configuring ECG device, saving measurements in chronological order, independently monitoring health, displaying ECG waveforms as reference data for	175	On-device electrodes 99 records 1000 meas./charge

		Clinically tested			medical specialists, printing the ECG as a useful means of providing important information to your doctor		
7	MD100E1 (Beijing Choice Electronic Tech Co., Ltd)	One channel ECG, 30 seconds recording 0,5-75 Hz bandwidth, sampling 250 Hz	USB	MD100E – allows continued recording then using SD card	Records are stored in internal memory or SD card and can be viewed using proprietary software on PC	220	On-device electrodes or disposable electrodes 500 meas./charge
8	MDA100A12 (Beijing Choice Electronic Tech Co., Ltd)					160	
9	MDA100B1 (Beijing Choice Electronic Tech Co., Ltd)					195	
10	EKG PEN (Beijing Choice Electronic Tech Co., Ltd)	One channel ECG, 30 seconds recording 1-40 Hz bandwidth, sampling 250 Hz				160	
11	Zenicor- EKG recorder (Zenicor Medical Systems AB)	10, 20 or 30 seconds, limb lead I registration by attaching two thumbs on the device	Built-in GSM/GPRS modem		Built-in mobile phone enables user initiated automatic sending of the ECG to the Internet connected ECG database with patients integrity secured. The ECG database can be reached by the care provider from any Internet connected computer.		On-device electrodes 200 records 500 meas./charge
12	eMotion ECG (by Mega Electronics Ltd)	Single channel ECG Has CE mark and FDA clearance.	CE mark and clearance.		eMotion Lab software for data handling and reviewing is included with all eMotion Faros sensors. More comprehensive HRV Scanner software for HRV data analysis can be purchased as an option. HRV Scanner allows you to visually follow up, interpret and create reports of stress and well-being through its	890	Wired 3 leads to standard disposable electrodes Up to 27 hours/charge
13	eMotion Faros 90°	One channel ECG recording (up to	USB download	Heart rate variability, 3D accelerometer,	user-friendly interface.	399	Disposable electrodes or

	(by Mega Electronics Ltd)	250 Hz sampling)		up to 2 months memory			chest-strap
14	eMotion Faros 180° (by Mega Electronics Ltd)	One channel ECG streaming (BT)/recording (up to 1000 Hz sampling)	Bluetooth/USB download	Heart rate variability, 3D accelerometer, 1 GB memory		494	
15	eMotion Faros 360°(by Mega Electronics Ltd)	Three channel ECG streaming (BT)/recording (up to 1000 Hz sampling)	Bluetooth/USB download	Heart rate variability, 3D accelerometer, temperature, breathing		990	
16	Actiwave Cardio (CamNtech)	One channel ECG up to 31 hours Widely used in scientific studies	USB	3-axes of acceleration	Data is stored on the PC in European Data Format (EDF+) files.	1010 EUR (Cardio unit) 440 EUR (CardioDock)	Has short lead, which simply clip onto two standard ECG pads worn on the
17	Actiheart (CamNtech)	One channel ECG up to 21 days Widely used in scientific studies				1200 EUR (Actiheart unit) + 465 EUR (Actiheart reader/charger)	chest. Also can be used textile chest strap.
18	ePatch ECG recorder ( DELTA Dansk Elektronik)	1 or 2 ECG channels with 128, 256, 512, 1024 samples/sec Frequency response 0.67 – 40 Hz	RF Zigbee (BLE, Wifi, 833/900) (options)		Customisable solution	Offers ePatch® technology platform for customers for developing and marketing own specific patch based solution under own brand	Customisable solution

	1	1	1	Table 5. Blood oxyge	enation (SpO2) mea			1
No.	Device	Measured parameters	Connectivity	Additional measurements	Compatibility	Comments on API, data gathering	Price, EUR	Other
1	Onyx II 9560 (Nonin)	hin) Range (SpO2): 0 to 100% SpO2 Accuracy (Arms) 70-100%: Oxygen Saturation Accuracy ± 2 digits		Pulse Rate Range: 18 to 321 beats per minute (BPM)	Bluetooth Health Device Profile (HDP), IEEE 11073 and Continua standards	OEM Development Kit containing the oximeters HDP and SPP communication profiles and demonstration software	330	Spot-check finger pulse oximeter
2	WristOx2 model 3150 (Nonin)	Oxygen Saturation Range (SpO2): 0 to 100% SpO2 Accuracy (Arms) 70-100%: Oxygen Saturation Accuracy ± 2 digits	Bluetooth 2.0, USB				800	Continuous measurements Wrist-worn wireless pulse oximeter Operating without Bluetooth: 48 h min Operating with Bluetooth: 24 Hours minimum
3	Model 3230 (Nonin)	Oxygen Saturation Range (SpO2): 0 to 100% SpO2 Accuracy (Arms) 70-100%: Oxygen Saturation Accuracy ± 2 digits	Bluetooth® Smart			OEM Development Kit	220	Spot-check finger pulse oximeter
4	iHealth Wireless Pulse Oximeter	SpO2 measuring range: 70-99% SpO2 accuracy: 70- 99%,±2%; <70%, no definition	Bluetooth 4.0 BLE	Pulse rate measuring range: 30-250bpm Pulse rate accuracy: ±2bpm or ±2% larger one	iOS 5.0 or higher	cloud enabled service https://cloud.ihealthlabs.com. Cloud service has API: http://developer.ihealthlabs.com/index.htm	80	Spot-check finger pulse oximeter
5	Withings Pulse O2	SpO2	Bluetooth 4.0	Heart rate, captures steps, distance walked, elevation climbed and calories burned, sleep duration	compatible with Bluetooth 2.0 Support for iOS 6.0 or higher and Android 2.3.3 +	Withings app for iOS or Android. Data storage in Withings HealthCloud. Has API: <u>http://oauth.withings.com/api</u>	120	Spot-check finger pulse oximeter 2 week between charges
6	Tinkė from Zensorium	SpO2 : 90 - 100% Blood oxygen saturation: +/- 1% in 96 - 100 % range; +/- 2% in the range below 96%	Bluetooth 4.0	Heart rate: 40 - 120 bpm Respiratory rate: 8 - 20 bpm	Android		130	Spot-check finger pulse oximeter 120 spot- checks/charge



# 2.4. Body composition and fluids monitoring

# 2.4.1. State of the art

Bioimpedance is a measure of the opposition to the flow of sinusoidal alternating current in a living organism. Resistance to the applied current occurs in the extracellular and intracellular compartments. Hindrance to the current occurs at the cell membrane and results in reactance or capacitance<sup>127</sup>.

The basic approach is an electro-physical model in which bio conductor volume is inversely related to R corrected for length or height  $(V = L^2 / R)^{128}$ .

## 2.4.1.1. Bioimpedance analysis

Resistance, measured at 50 kHz or pre-determined multiple frequencies including 50 kHz, body weight, age, and gender were independent variables included in the development of regression models to predict TBW and fat-free mass (FFM). Although this approach resulted in very good correspondence between measured and predicted values in healthy people, the errors in prediction were large (5-10%) whereas application of these predictions models in clinical groups yielded significant differences<sup>129</sup>. Furthermore, analysis of errors revealed wide ranges of error (95% confidence intervals) in predictions of change in body composition for an individual<sup>130</sup>.

Unfortunately, in patients with abnormal hydration, these BIA estimates are biased<sup>131</sup>.

## 2.4.1.2. Bioimpedance spectroscopy (BIS)

This method uses measurements of R made sequentially at frequencies of 5 kHz to 2 MHz. It extrapolates R values from low and high frequency to estimate R of extracellular and intracellular fluids, respectively, with the Cole-Cole model. These values are used to calculate extra- and intracellular resistivities with the Hanai model, which with body weight and height to compute TBW and extracellular water (ECW) and estimate intracellular water (ICW; TBW- ECW). Although theoretically appealing, BIS significantly underestimates TBW in clinical groups and is imprecise for estimates of change in TBW and ECW among individuals<sup>132</sup>, and provides large ranges of error for predictions of individual changes in ICW for individuals<sup>133</sup>.

Reliance on multiple regression predictions models suffers from various errors. Technical sources include errors of measurement of bioimpedance (1% at 50 kHz), reference methods including isotope dilution (2-5%) and the standard error of the estimate generated in the regression model (5-10%). These errors propagate and contribute to the imprecision of an estimate for an individual. Electrical and biological errors also contribute as do invalid assumptions of normal and constant hydration of the fat-free body, uniform

<sup>&</sup>lt;sup>127</sup> Lukaski HC. Biological indices considered in the derivation of the bioelectrical impedance analysis. Am J Clin Nutr 1996;64(Suppl): 397S-404S.

<sup>&</sup>lt;sup>128</sup> Hoffer EC, Meador CK, Simpson DC. Correlation of whole body impedance with total body water volume. J Appl Physiol 1969; 27: 531-534.

<sup>&</sup>lt;sup>129</sup> Buchholz AC, Bartok C, Schoeller DA. The validity of bioelectrical impedance models in clinical populations. Nutr Clin Prac 2004; 19: 433-446.

<sup>&</sup>lt;sup>130</sup> Savastano S, Belfiore A, Di Somma C et al. Validity of bioelectrical impedance analysis to estimate body composition changes after bariatric surgery in premenopausal women.Obes Surg 2010; 20: 332-339.

<sup>&</sup>lt;sup>131</sup> Piccoli A; The Italian Hemodialysis-Bioelectrical Impedance Analysis (HD-BIA) Study Group. Identification of operational clues to dry weight prescription in hemodialysis using bioimpedance vector analysis. Kidney Int 1998; 53(4): 1036-1043.

<sup>&</sup>lt;sup>132</sup> Cox-Reijven PL, van Kreel B, Soeters PB. Bioelectrical impedance measurements in patients with gastrointestinal disease: validation of the spectrum approach and a comparison of different methods for screening for nutritional depletion. Am J Clin Nutr 2003; 78: 1111-1119.

<sup>&</sup>lt;sup>133</sup> Mager JR, Sibley SD, Beckman TR et al. Multifrequency bioelectrical impedance analysis and bioelectrical impedance spectroscopy for monitoring fluid and body cell mass changes after gastric bypass surgery. Clin Nutr 2008; 27: 832-841.



conduction of the applied current and constant body geometry in cylindrical shape in pathophysiological states<sup>134</sup>.

#### 2.4.1.3. Bioimpedance vector analysis

Bioelectrical impedance vector analysis (BIVA) allows a direct assessment of body fluid volume through patterns of vector distribution on the R-Xc plane. Using patterns of the resistance-reactance graph (RXc graph) of BIVA it is possible to rank both hydration and mass of soft tissues. Ranking can be performed on repeated measurements of an individual subject or among different subjects. Indeed, the intersubject variability of Z is represented by the bivariate normal distribution with elliptical probability regions: 50%, 75%, and 95% tolerance ellipses for individual vectors. R and Xc values are normalized for subjects' height (H) and expressed as R/H and Xc/H (Ohm/m)<sup>135</sup>.

As with ECG, BIVA uses patterns of impedance vector distribution, which are associated with clinical conditions, without the need of equations or body weight. Changes in tissue hydration status below 500 mL are detected and ranked. A simple algorithm with few operational rules has been derived for interpreting impedance vector position and migration on the R-Xc graph at the bedside in any clinical condition<sup>136</sup>.

Vector position on the R-Xc graph is interpreted following two directions on the R-Xc plane, 1) vector displacements parallel to the major axis of tolerance ellipses indicate progressive changes in tissue hydration, that is dehydration with long vectors, out of the upper pole of the 50% ellipse, and fluid overload with apparent edema, with short vectors, out of the lower pole of the 50% ellipse; and 2) peripheral vectors lying in the left side of the major axis, or in the right side of the major axis of tolerance ellipses indicate more or less cell mass, respectively. Fluid removal in malnourished patients is associated with a flat vector migration to the right side, due to an increase in R without a proportional increase in Xc caused by severe loss of soft tissue mass. This pattern is never observed in vectors lying on the left side of the tolerance ellipses<sup>136</sup>.

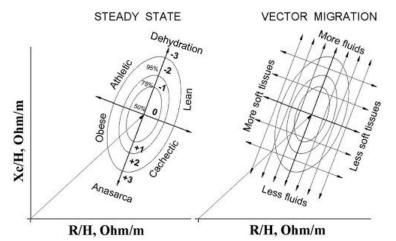


Figure 40. BIVA. The ellipsis describes the hydration and nutrition status domain. Optimal status is at the center of the domain and vector migration toward different directions represents an alteration of the nutritional/hydration status of the patient. Subsequent examinations are useful to establish a trend<sup>137</sup>.

Volume assessment with BIVA has excellent correlation with the gold standard of deuterium dilution (r = 0.996)<sup>138</sup>, but BIVA results are available within 1 minute and at much less expense<sup>139</sup>. BIVA has been successfully used to both diagnose and manage AHF<sup>140</sup>.

<sup>&</sup>lt;sup>134</sup> Foster KR, Lukaski HC. Whole body impedance: what does it measure? Am J Clin Nutr 1996; 64(Suppl): 388S-396S.

<sup>&</sup>lt;sup>135</sup> Piccoli A, Nigrelli S, Caberlotto A et al. Bivariate normal values of the bioelectrical impedance vector in adult and elderly populations. Am J Clin Nutr 1995; 61(2): 269-270.

<sup>&</sup>lt;sup>136</sup> Piccoli A. Patterns of bioelectrical impedance vector analysis: learning from electrocardiography and forgetting electric circuit models. Nutrition 2002; 18(6): 520-521.

<sup>&</sup>lt;sup>137</sup> Claudio Ronco, Manish Kaushik, Roberto Valle, Nadia Aspromonte, W. Frank Peacock IV. Diagnosis and Management of Fluid Overload in Heart Failure and Cardio-Renal Syndrome: The "5B" Approach, 2012.

<sup>&</sup>lt;sup>138</sup> Kushner R, Schoeller D, Fjeld C et al. Is the impedance index (ht2/R) significant in predicting total body water? Am J Clin Nutr 1992; 56(5): 835-839.



The emergency department (ED) use of BIVA for diagnosis and disposition has been recently reported in a prospective study of 101 patients presenting to the ED with suspected volume abnormalities<sup>141</sup>; of these 31 (30%) were defined as volume overloaded, of which (25) 80% were due to AHF. In this analysis, height corrected reactance (Xc/H) and resistance (R/H), and calculated bioimpedance (Z) were associated with volume overload. Reactance was nearly 38% less in volume overloaded patients, while R/H and Z were about 30% less. Further, Z was the most accurate predictor of volume overload (c statistic = 0.86) when compared to all clinical predictors, including paroxysmal nocturnal dyspnea (p < 0.0001), orthopnea (c-stat 0.63, p = 0.0005), rales (c-stat 0.72, p < 0.01), jugular venous distension (c-stat 0.66, p < 0.0002), edema (c-stat 0.71, p < 0.01), or the presence of an S3 or S4 (c-stat 0.53, p = 0.0001). Only a BNP > 100 pg/mL or chest x-ray findings of overload performed equally as well as Z (BNP c-stat 0.91, p = 0.14, x-ray c-stat 0.76, p = 0.11). There was no correlation between Z and BNP (r = -0.1299, p = 0.28). At a cut-off value of Z ≤ 225 W/m, BIVA had a sensitivity and specificity of 77% and 80% for detecting volume overload, respectively.

BIVA measures were valuable for predicting the need for volume reduction therapy (defined as receiving loop diuretics), with superior predictive capability (c-stat 0.83), compared to all clinical parameters and the chest x-ray. Only a BNP > 100 pg/mL was comparable to BIVA for predicting the need for volume reduction therapy (c-stat 0.82, p = 0.48)<sup>141</sup>.

Finally, BIVA values were associated with ED disposition and prognosis. Patients discharged home had higher Xc/H (28.1 vs 22.8 W/m, p = 0.002), R/H (266.9 vs 224.7, W/m, p = 0.002) and Z (268.5 vs 225.9, W/m, p = 0.001). In patients hospitalized, Xc/H (r = -0.36, p = 0.01) and PA (-0.31, p = 0.03) had weak correlation with the length of stay in the hospital <sup>141</sup>.

A study was performed to investigate BIVA's ability to help attain dry weight in 94 patients with refractory congestive heart failure, gave high dose furosemide and monitored volume status changes with BIVA at admission and 6 days after. They found that there was a 14% increase in R/H and a 33% increase in Xc/H<sup>142</sup>. In a pilot study of 186 hospitalized AHF patients, BNP and serial BIVA measurements were used to guide fluid management<sup>143</sup>. This strategy was then validated in 166 AHF patients discharged based on BIVA and BNP targets. They reported lower 6-month readmission rates and cost of care<sup>144</sup>.

The combined use of both BIVA and BNP improves the management of heart failure patients because it is useful to reach a faster and more accurate diagnosis, it is a valid support to distinguish cardiogenic dyspnea from non-cardiogenic dyspnea and supports decisions about diuretic therapy. Furthermore, the combination of BIVA and BNP identifies patients with higher probability of events (death or rehospitalisation)<sup>145</sup>.

BIVA has been used to diagnose and guide therapy. In one study, BIVA determined the adequacy of ultrafiltration in more than 3,000 hemodialysis patients. Short vector lengths corresponded to greater soft-tissue hydration (less adequate ultrafiltration). Defining a vector length of 300 to 350 ohm/m as the referent category, the risk of death was approximately 50% and 180% higher for those with inadequate volume removal as reflected by a BIVA vector length of 200 to 250 and less than 200 ohm/m, respectively<sup>146</sup>.

<sup>&</sup>lt;sup>139</sup> Piccoli A. Whole body- single frequency bioimpedance. Contrib Nephrol 2005; 149: 150-161.

<sup>&</sup>lt;sup>140</sup> Parrinello G, Paterna S, Di Pasquale P et al. The Usefulness of Bioelectrical Impedance Analysis in Differentiating Dyspnea Due to Decompensated Heart Failure. J Card Fail 2008; 14(8): 676-686.

<sup>&</sup>lt;sup>141</sup> Tuy T, Talati A, Fiessinger L et al. Detection of Acute Heart Failure in the Emergency Department with Bioimpedance Vector Analysis. Ann EM 2011 abstract presented at the American College of Emergency Physician's Scientific Assembly, San Francisco (CA), Oct, 2011.

<sup>&</sup>lt;sup>142</sup> Paterna S, Di Pasquale P, Parrinello G et al. Changes in brain natriuretic peptide levels and bioelectrical impedance measurements after treatment with high-dose furosemide and hypertonic saline solution versus high-dose furosemide alone in refractory congestive heart failure: a double-blind study. J Am Coll Cardiol 2005; 45(12): 1997-2003.

<sup>&</sup>lt;sup>143</sup> Valle R, Aspromonte N, Giovinazzo P et al. B-type natriuretic Peptide-guided treatment for predicting outcome in patients hospitalized in sub-intensive care unit with acute heart failure. J Card Fail 2008; 14(3): 219-224.

<sup>&</sup>lt;sup>144</sup> Valle R, Aspromonte N, Carbonieri E et al. Fall in readmission rate for heart failure after implementation of B-type natriuretic peptide testing for discharge decision: a retrospective study. Int J Cardiol 2008; 126(3): 400-406.

<sup>&</sup>lt;sup>145</sup> Di Somma S., De Berardinis B, Bongiovanni C et al. Use of BNP and bioimpedence to drive therapy in heart failure patients. Cong Heart Fail 2010; 16 (suppl 1): S56-S61.

<sup>&</sup>lt;sup>146</sup> Pillon L, Piccoli A, Lowrie EG, Lazarus JM, Chertow GM. Vector length as a proxy for the adequacy of ultrafiltration in hemodialysis. Kidney Int. 2004;66:1266-71.



## 2.4.2. Comparative analysis of commercial devices

#### 2.4.2.1. Fresenius Body Composition Monitor

Fresenius Body Composition Monitor<sup>147</sup> (Figure 41) allows the detection of overhydration by determining the quantitative amount of excess fluid in the body. Has no API.



Figure 41. Fresenius Body Composition Monitor<sup>148</sup>

Main features and specifications:

- Has been specifically designed for patients with kidney failure
- Overhydration [L]
- Urea distribution volume (V)
- Total body water (TBW), extracellular (ECW) and intracellular water (ICW)
- Nutritional status
- Lean Tissue Index (LTI)
- Fat Tissue Index (FTI)
- Body Cell Mass (BCM)
- Price: ~11571 EUR + dedicated electrodes 5,78 EUR pcs/measurement, excluding VAT.

#### 2.4.2.2. Renal EFG for Nephrology

Renal EFG for Nephrology (Figure 42) by EFG Diagnostics Ltd<sup>149</sup> is small and light in weight, the battery operated RenalEFG is easy to take to your patient for fast and accurate fluid status measurements. The touch sensitive colour screen provides ease of use and fast informative display of patient results in just a few seconds. Results are plotted on a Biavector display for easy interpretation and can be printed on the integrated printer BIVAtrode electrodes can be quickly and easily fixed to the patients hand and foot for painless and accurate fast readings. This ensures rapid patient acceptance of the test.



Figure 42. Renal EFG for Nephrology Monitor <sup>150</sup>

<sup>&</sup>lt;sup>147</sup> <u>http://www.bcm-fresenius.com/</u>

<sup>&</sup>lt;sup>148</sup> <u>http://www.bcm-fresenius.com/images/0.AABC.jpeg</u>

<sup>&</sup>lt;sup>149</sup> <u>http://www.efgdiagnostics.com/products.html</u>

<sup>&</sup>lt;sup>150</sup> http://www.efgdiagnostics.com/images/renal1.jpg



Main features and specifications:

- Resistance measurement in 0 999 Ohm range with ±0.1 Ohm accuracy
- Reactance measurement in 0 999 Ohm range with ±0.5 Ohm accuracy
- Results are plotted on a Biavector display for easy interpretation
- Hydration status
- Renal EFG is supplied with "Cardiogram Software" which enables data to be transferred via the included USB cable to a computer for storage, post processing and reporting.
- Battery operated up to 8 hrs., recharge 4 hrs.
- Dimensions of 290 mm x 200 mm x 75.6 mm
- Class II medical device
- Price: ~7000 EUR excluding VAT + pack of dedicated electrodes 35 EUR for 10 measurements.

#### 2.4.2.3. iHealth HS5 body composition scales

Wireless body analysis scale iHealth HS5 (Figure 43) by iHealth labs Inc.<sup>151</sup> is a personal use automatic electronic measurement device with WiFi communication.



Figure 43. Wireless body analysis scale iHealth HS5<sup>152</sup>

Main features and specifications:

- Wireless communication: WiFi, settings are transferred via Bluetooth;
- Free iHealth MyVitals mobile app is available for iPhone, iPad or iPod touch and for Android. iHealth
  Labs application automatically transfers data to the cloud enabled service
  https://cloud.ihealthlabs.com, using which consumers are able to see a more comprehensive view of
  their vitals and easily share information with healthcare professionals or others.
- Body fat measurement range: 5%-65%, ±1%
- Body water measurement range: 20%-85%, ±1%
- Visceral fat rating range: 1-59
- Body weight: ±0.5kg (5kg~40kg); ±(1%+0.1kg)(40kg~150kg)
- Body muscle mass:  $\pm(1\% + 0.1 \text{ kg})$
- Bones mass: ±0.3 kg
- Visceral fat rating: ±2
- DCI (Daily Calorie Intake): ±200kcal
- Size: 14.96" x 12.20" x 1.38" (380 mm × 310 mm × 35 mm)

<sup>&</sup>lt;sup>151</sup> <u>http://www.ihealthlabs.com/wireless-scales/wireless-body-analysis-scale/</u>

<sup>&</sup>lt;sup>152</sup> <u>http://www.ihealthlabs.com/files/3814/0233/2241/iHealth\_HS5\_Hero2.png</u>



- Weight: 3.3 lbs/1.5 kg (excluding battery)
- Power: 4 × 1.5V AA batteries lasts approx. 3 months with daily usage
- Price: 119.99 EUR

## 2.4.2.4. Medisana body Analysis Scales

The body analysis scale BS 440 connect<sup>153</sup>, BS 430 connect<sup>154</sup> and TargetScale 2<sup>155</sup> analyses most important factors indicating bodily fitness, such as body fat, amount of body water, and muscle mass. The ITO electrodes are ultrathin with a vacuum-metalized surface on the BS 440 connect, stainless steel electrodes for the BS 430 connect and TargetScale 2 not only delivers measurements for up to eight users and shows them on the large backlit display, but can also transmit them by Bluetooth® to the VitaDock+ app on iOS and Android devices and then to VitaDock® Online. Provides API for easy integration of cloud services.



Figure 44. Medisana wireless body analysis scales BS 440 connect<sup>153</sup> (left), BS 430<sup>154</sup> connect (middle) and TargetScale 2<sup>155</sup> (right)

Main features and specification:

- Measurement of weight, body fat, body water, muscle percentage and bone weight
- Determination of the BMI value
- Integrated calorie requirement analysis (BMR)
- High-quality ITO electrodes (BS 440 connect)
- Convenient "step-on" switch
- Large easy-to-read LCD display with backlight
- Toggles between kg, lb and st
- Four high-precision strain gauge sensors for accurate results
- Automatic recognition of up to 8 users
- Bluetooth® data transfer to the VitaDock+ app for iOS and Android and to VitaDock Online, TargetScale 2 body composition scales works with IOS devices only.
- Prices:
  - 72 EUR for Model BS 440 connect
  - 64 EUR for Model BS 430 connect
  - 80 EUR for Model TargetScale 2

<sup>&</sup>lt;sup>153</sup> <u>http://www.medisana.com/en/Mobile+Health/Body+Analyses+Scales/BS+440+Body+analysis+scale+with+Bluetooth.html</u>

<sup>&</sup>lt;sup>154</sup> <u>http://www.medisana.com/en/Mobile+Health/Body+Analyses+Scales/BS+430+Body+analysis+scale+with+Bluetooth.html</u>

<sup>&</sup>lt;sup>155</sup> <u>http://www.medisana.com/en/Mobile+Health/Body+Analyses+Scales/TargetScale+2+Body+Analysis+Scale+with+Target+Funktion.html</u>



#### 2.4.2.5. Tanita body composition Analysers

The BC-1000plus Body Composition Monitor<sup>156</sup> (Figure 45) by Tanita<sup>157</sup> offers consumers the ability to wirelessly link data to remote displays and a personal computer with supplied USB ANT+ stick. Works with Windows XP/Vista and Windows 7. Not compatible with MAC, but Apple iPad/iPhone/iPod Touch devices can connect using the optional Tanita Wi-Fi Network Adapter.



Figure 45. BC-1000plus ANT+ Radio Wireless body composition Monitor<sup>158</sup>

Main features and specification:

- Weight 0 200 kg
  - Body Fat %
  - Body Water %
- Muscle Mass
- Physique Rating
- Daily Caloric Intake (DCI)
- Metabolic Age
- Bone Mass
- Visceral Fat Rating
- Computer Interface: ANT+™ enabled with wireless ANT+™ USB Stick (included)
- Serial pairing with Tanita remote display
- FREE Healthy Edge Lite software (up to 8 users)
- No display on platform, transmits data to remote display and personal computer
- Power: 4 × 1.5V AA batteries
- Price: 230 EUR

## 2.4.2.6. Beurer diagnostic scale BF800

BF 800 diagnostic scale<sup>159</sup> (Figure 46) by Beurer GmbH<sup>160</sup> records numerous other health values such as body mass index (BMI), water content, muscle mass, bone mass, basal metabolic rate (BMR) and active metabolic rate (AMR) and transfers this data directly to the smartphone via Bluetooth® Smart, where users can manage their personal statistics in the free HealthManager app.

<sup>&</sup>lt;sup>156</sup> <u>http://www.thecompetitiveedge.com/shop/item/123-productId.184550699\_123-catId.176160866.html</u>

<sup>&</sup>lt;sup>157</sup> <u>http://www.tanita.com/en/bc1000plusbk/</u>

<sup>&</sup>lt;sup>158</sup> <u>http://www.tanita.com/modules/imageresizer/c08/400/e72203c07f/250x250.jpg</u>

<sup>&</sup>lt;sup>159</sup> http://www.beurer.com/web/en/products/weight/diagnostic\_scales/BF-800-black

<sup>&</sup>lt;sup>160</sup> <u>http://www.beurer.com/</u>





Figure 46. BF 800 black Wireless body composition scale

Main features and specification:

- Bluetooth SMART technology for wireless communication
- Weight 0 1800 kg
- Body Fat %
- Body Water %
- Muscle Mass
- Basal metabolic rate in kcal (BMR)
- Active metabolic rate in kcal (AMR)
- Bone Mass
- Power: 3 × 1.5V AAA batteries
- Price: 125 EUR

#### 2.4.3. Summary

Table 6 summarizes main features and specifications of the analysed devices for body composition state monitoring for everyday use by the patients. The main criteria for the analysis: highest quality of measured parameter, newest connectivity technologies (Bluetooth SMART), additional measurements that could enable to use the device for measuring other observables, availability of API, price level. The collected parameters in the table were analysed and marked by the colours: **green** colour means "excellent", **yellow** colour means "satisfactory" and no colour means "neutral". The best one was marked by green colour, the second one – by yellow colour.

Summarising, for the monitoring of body composition parameters is recommended Medisana BS 440 connect, or BS 430 connect, or iHealth HS5 Wireless body analysis scales.

											Т	able	e 6. E	Body composition	n Analysis Scales		
Device	Max Weight, kg	FAT %	FAT Mass	Fat Eree Mass	Muscle Mass	Total Body	Water Mass Total Body	Water %	BMR	DCI	Metabolic Age	Bone Mass	Visceral Fat Rating	Connectivity	Availability of API, data gathering method	Price, EUR	Additional Information
Tanita SC331S	270	o	o	о	0	о	o		э	0	0	0	0	USB	Open format direct conn.	2320	Degree of Obesity, Ideal Body Weight, Body Type, Impedance
Tanita MC780	270	о	o	о	0	о	o	C	С		0	о	0	USB	CSV file on SD card and USE transfer	4820	Reactance, Resistance, Phase angle, Body Type, Impedance, Segmental measures
Tanita BC730	150	o			о		o	C	С		0	о	о			50	Body Type
Tanita BC-545	150	o			о		o	C	С		0	o	о			200	clock/calendar, Body Type, Segmental measures
Tanita BC-1000	200	o			0		o	C	с	D	0	о	0	ANT+ USB stick	App for PC	230	Body Type; Windows, MAC, Garmin, iPhone compatibility
Beurer BG64	150	о			о		o	C	С			о		USB	App for PC	60	433MHz RF
Beurer BG900	150	о			о		o	C	с	0		о		RF to LAN adapter		130	
Beurer BF100	150	о			о		o	C	с	0		о		USB		136	Removable display, Segmental measures
Beurer BF480	150	о			о		o					о		USB		42	
Beurer BF800	180	o			о		o	C	с	0		о		Bluetooth SMART		125	
Microlife WS 80	150	o			о		o	C	С			о				54	
Microlife WS 100	150	o					o									38	
SECA mBCA 515	300	o	o	o	о	o		cw/ cw	С					LAN and WiFi		10300	Impedance
KERN & SOHN MFB	150	0			0	о						0				90	
Biospace InBody230	250	o	o	ο	о	o	o	c	c			0		LAN ,USB		4100	No Empirical Estimation, Impedance, Segmental measures
Medisana BS 440 Connect	180	0			0		o			0		0		Bluetooth SMART	Medisana Cloud API	72	

Medisana BS 430 Connect	180	о			0	C	0		0		0		Bluetooth SMART	Medisana Cloud API	64	
Medisana TargetScale 2	180	o			о	C	C		0		о		Bluetooth	Medisana Cloud API	80	
iHealth HS5	150	o		о	о	C	D	o	о	о	о	о	Wifi, settings vi Bluetooth	a iHealth Cloud API	110	
Withings WS-50	150	o											Wifi, Bluetoot SMART	Withings HealthCloudAPI	150	Heart Rate, Temperature, CO2
Marsden MBF-6000	300	o	о	о		C	C	о					RS232	Direct transfer	354	Impedance



# 2.5. Physical activity and sleep monitoring

#### 2.5.1. State of the art

There are many inexpensive but subjective methods to monitor physical activity: diaries, questionnaires, surveys, clinical observation, functional tests and even more. However, results then depend on patient recall, clinician observation and subjective interpretation of these two combined, which makes these methods unreliable source. On the other hand, such objective methods as kinematic and kinetic analyses, force plate analysis, indirect calorimetry, double labelled water analysis or video recording provide much more accurate information but are expensive, time consuming or requiring a special laboratory set-up.

Body-fixed MEMS motion sensors – accelerometers, altimeters, gyroscopes - are commonly used and have been widely accepted as useful tools to measure human body movements. The energy expenditure is a bit more challenging while it does not reflect on the movements unambiguously. Heart rate, on the contrary, contains information of physical effort required. Therefore, more and more physical activity tracking is accompanied by the heart rate sensors. Even more, all kinds of physical activity results in changes in the skin: some level of increased perspiration, sweat glands activity, increased temperature. Consequently, monitoring of these additional parameters is also sometimes employed.

To conclude, it may be understood that there are many parameters to be monitored in order to evaluate physical activity. Of course, more parameters results not only in better accuracy but in higher complexity too. Therefore, sensors included and parameters obtained varies from device to device.

Signals: acceleration, angular velocity, altitude, ECG, PPG, galvanic skin response, temperature, humidity.

Parameters: steps, distance, calories burned, stairs climbed, sleep quality, hours slept, heart rate, counts, MET, duration of activity, intensity of activity.

#### 2.5.2. Comparative analysis of commercial devices

#### Fitbit One

The One<sup>161</sup> uses a MEMS 3-axis accelerometer and altimeter that measures motion and changes in altitude. This tracker is able to determine steps, distance travelled, calories burned, stairs climbed and sleep quality. It also contains vibration motor, which enables vibrating alarms feature. This tracker can be clipped to the clothes via silicone or metal clip during the day (see Figure 47) and can also be worn using additional wristband for sleep. The battery lasts a minimum of 10 days up to 14 days. It can be charged with the provided battery charger, which plugs into USB drive. The device synchronizes data automatically anytime it is near the Bluetooth 4.0 LE (BLE) sync dongle, which should be plugged in the PC. It can also synchronize with BLE enabled smartphone, using Fitbit provided app. Fitbit One weighs only 8 grams and costs \$99.95 USD.



Figure 47. Fitbit One wireless activity and sleep tracker<sup>162,163</sup>

<sup>&</sup>lt;sup>161</sup> <u>http://www.fitbit.com/one</u>

<sup>&</sup>lt;sup>162</sup> http://cdn.gizmoreport.com/wp-content/uploads/2013/06/FitBit-One-Fitness-Tracker.jpeg



## Fitbit Flex

The Flex<sup>164</sup>, which is shown in Figure 48, is very similar to the One in terms of features and hardware. It uses 3-axis accelerometer, is able to determine steps, distance travelled, calories burned and sleep quality and contains vibration motor. However, it lacks of altimeter and therefore ability to count stairs climbed. One more difference from the One is that Flex is supposed to be worn on the wrist all the time. Lithium-polymer battery lasts around 5 days, which is lower comparing to the One. It employs the same sync technique as One and costs exactly the same \$99,95 USD. Fitbit also provides cloud based API for all of their devices.



Figure 48. Fitbit Flex wristband<sup>165,166</sup>

## *iHealth wireless activity and sleep tracker*

iHealth activity tracker<sup>167</sup> is simple wristwatch type tracker (see Figure 49) employing accelerometry to count steps, estimate calories burned and travelled distance. It also estimates hours slept, times one have been awaken and calculates sleep efficiency score. Even more, it can vibrate to be used as an alarm clock. As it can be seen from these specifications, this tracker is a lot like Fitbit Flex. The main differences are large display and of course the price – this tracker costs \$59,95 USD. It connects with all iOS and some Android devices via Bluetooth 4.0 LE. The tracker can be worn on the wrist or on the waist. When wearing on the waist, the provided clip must be used, because it triggers the tracker to switch from wrist mode to waist mode, for better accuracy. iHealth offers cloud based API.



Figure 49. iHealth physical activity and sleep tracker<sup>168</sup>

<sup>&</sup>lt;sup>163</sup> <u>http://cnet2.cbsistatic.com/hub/i/r/2013/04/29/97c2d77b-67c2-11e3-a665-14feb5ca9861/thumbnail/770x433/f810eec228ae5fe132c52f14463449dd/Fitbit\_One\_35537316\_07\_540x386.jpg</u>

<sup>&</sup>lt;sup>164</sup> <u>http://www.fitbit.com/flex</u>

<sup>&</sup>lt;sup>165</sup> <u>http://www.clove.co.uk/product-images/fullsize/fitbit-flex-gad-fflex.jpg</u>

<sup>&</sup>lt;sup>166</sup> <u>http://static5.fitbit.com/simple.b-dis-jpg.h4a6afbfd3ec59fbfcea132e851dfe306.pack?items=%2F</u> content%2Fassets%2Fonezip%2Fimages%2Ffeatures-content%2Fflex%2Fflex\_04.jpg

<sup>&</sup>lt;sup>167</sup> http://www.ihealthlabs.com/fitness-devices/wireless-activity-and-sleep-tracker/

<sup>&</sup>lt;sup>168</sup> <u>http://www.ihealthlabs.com/files/6514/0233/4034/iHealth\_AM3\_Hero2.png</u>



#### Medisana VIFIT Connect activity tracker

VIFIT<sup>169</sup> is another inertial measurement based activity tracker, using accelerometer and altimeter. It counts steps, estimates calories burned, distance walked, the duration of the activity, sleep duration and sleep quality. Tracker can store data of last 15 days and transfer it to the VitaDock+ app on iOS or Android smartphone via Bluetooth 4.0 LE. The device has OLED display, one button and scratch resistant housing. Rechargeable lithium-ion battery lasts for 5-7 days. VIFIT can be worn using included wrist strap (see Figure 50) or simply in the pocket. Medisana offers Vitadock API for all of their devices.



Figure 50. Medisana VIFIT activity and sleep tracker<sup>170</sup>

#### Scosche RHYTHM+ armband pulse monitor171

This activity monitor tracks only the heart rate and is suited to wear on the lower arm near the elbow or on the upper arm. This differs from all other wristwatch/wristband type trackers employing inertial sensors. The armband uses two green light emitting diodes (LED) and one yellow LED, which should be suited for darker skin. The device has Bluetooth 4.0 LE and ANT+ connectivity. Even more, it is able to communicate via both channels at the same time. Wireless connection allows distance up to 30 meters. This armband works with most popular health and fitness apps, including DigiFit, RunKeeper, MapMyFitness, Strava. However, it does not have any display or indicator and contains only one button, therefore it cannot be used alone. On the other hand, it allows the construction to meet IP67 waterproof standard. Rechargeable battery provides up to 8 hours of working time. The armband costs about \$80 USD.



Figure 51. The Scosche RHYTHM armband pulse monitor<sup>172</sup>

<sup>&</sup>lt;sup>169</sup> <u>http://www.medisana.com/en/Sport/Activity+Tracker/ViFit+connect+Activity+Tracker.html</u>

<sup>&</sup>lt;sup>170</sup> <u>http://en.factoryprices.de/product/medisana-76415-vifit-connect-activity-tracker-168576.html</u>

<sup>171</sup> http://www.scosche.com/rhythm+

<sup>&</sup>lt;sup>172</sup> <u>http://www.notebookcheck.net/fileadmin/Notebooks/News/\_nc/Scosche\_RHYTHM\_armband\_heart\_rate\_monitor.jpg</u>



#### Samsung Gear Live

Samsung Gear Live<sup>173</sup> is new Android smart watch in Samsung Gear series. It is available since 7<sup>th</sup> of July, 2014 in USA and Canada at the cost of \$199 USD. The device includes accelerometer, digital compass, gyroscope and optical heart rate monitor. It is similar to other Gear series smart watches, mostly Samsung Gear Neo. The main difference is that Live runs Google's new Android Wear software. It shows notifications, can use voice commands and integrates with some of Android phone apps. What concerns heart rate sensor, some reviews have evaluated it well<sup>174</sup>. If for some reason heart rate cannot be obtained, the watch helpfully offers to tighten the strap. The battery should last around a day or little more. That means the watch should be recharged every night, or at least every morning. Charging is accomplished via snap-on module to maintain IP67 water and dust resistance.



Figure 52. Samsung Gear Live wristwatch<sup>175</sup>

Hardware specifications:

- 1,63" AMOLED display,
- 1,2 GHz processor,
- 512 MB RAM,
- 4 GB internal storage,
- 300 mAh battery,
- weight of 59 grams.

## Adidas Smart Run

Adidas has miCoach products line, which includes chest strap heart rate monitors, speed monitors, and even a smart ball. One of the products is wristwatch called Smart Run<sup>176</sup>, which is showed in Figure 53. It contains accelerometer, GPS transceiver, optical heart rate monitor, therefore it can track speed, location, path and heart rate. It can also serve as a music player. While it enables Bluetooth 4.0 communication, data can be synced only via USB charging dock. The watch runs re-skinned Android 4.1 interface, but offers no API. So far, there is an ability to export mapped runs. It was stated by Adidas, that there would be full API in the future<sup>177</sup>. The main disadvantages of the unit are low battery life (up to 8 hours) and high cost – \$399 USD.

Hardware specifications:

- 1.45-inch transflective touchscreen colour display (184 x 184),
- 1.2GHz dual-core Texas Instruments OMAP4430 (ARM Cortex-A9) processor,
- 512MB of RAM,

<sup>&</sup>lt;sup>173</sup> <u>http://www.samsung.com/global/microsite/gear/gearlive\_features.html</u>

<sup>&</sup>lt;sup>174</sup> <u>http://www.theguardian.com/technology/2014/jul/11/google-smartwatches-review-lg-g-watch-samsung-gear-live-android-wear</u>

<sup>&</sup>lt;sup>175</sup> <u>http://www.downloadtizenapps.com/wp-content/uploads/2014/06/Gear-2-Neo-and-Gear-Live-Specs.png</u>

<sup>&</sup>lt;sup>176</sup> https://micoach.adidas.com/us/smartrun

<sup>&</sup>lt;sup>177</sup> http://www.engadget.com/2013/11/19/adidas-micoach-smart-run-review/



- 4GB of storage (3GB of which is user accessible),
- 410mAh battery,
- weight of 80.5 grams.



Figure 53. Adidas SmartRun wristwatch<sup>178,179</sup>

## Adidas Fit Smart

On 9<sup>th</sup> of July, Adidas officially announced another fitness tracker called Fit Smart<sup>180</sup> (see in Figure 54) which should be available for purchase in August. It is known that this device includes accelerometer and optical heart rate sensor. It can display pace, calories, time, distance and heart rate on the LED matrix display. Battery holds up to 5 hours in total, or up to 5 days if the workout lasts for 1 hour per day, as it is specified. While not in the workout mode, the tracker can show time on a button press. The Fit Smart is charged via special USB charging station to improve waterproofing. Talking about connectivity, it uses Bluetooth 4.0 LE to synchronize with Adidas miCoach fitness apps on Android or iOS. There no information about availability of the API. In a Google I/O Keynote presentation Adidas was shown as a part of Google Fit platform and some rumours have been spread about the Fit Smart integration into it. However, there are no official announcements at the moment. The price of the device is much lower than the Smart Run wristwatch, but still in the middle price range - \$199 USD.



Figure 54. Adidas FitSmart wristwatch<sup>181</sup>

Hardware specifications:

- soft touch silicon strap,
- 17x11 LED matrix,
- 200 mAh lithium ion battery,

<sup>&</sup>lt;sup>178</sup> <u>http://theawesomer.com/photos/2013/10/adidas\_micoach\_smart\_run\_t.jpg</u>

<sup>&</sup>lt;sup>179</sup> <u>http://www.digitaltrends.com/wp-content/uploads/2013/10/smart-run-adidas.jpg</u>

<sup>&</sup>lt;sup>180</sup> http://www.cnet.com/news/adidas-micoach-fit-smart-wearable-activity-tracker/

<sup>&</sup>lt;sup>181</sup> <u>http://9to5mac.files.wordpress.com/2014/07/adidas-fit-smart-01.jpg</u>



- up to 5 hours,
- up to 10 hours data storage,
- weight of 50 grams.

## 2.5.3. Smartphone based monitoring

#### 2.5.3.1. Workout tracking

#### Endomondo Sports Tracker



Figure 55. Endomondo Sports Tracker interface<sup>182</sup>

Endomondo<sup>182</sup> allows tracking any distance-based sport using GPS on the smartphone. The app shows duration of the workout, speed, distance, calories and other averaged parameters. It also gives audio feedback, allows entering workouts manually, and works with BT, BLE and ANT+ heart rate monitors. Interesting point of this app is social challenges, where one can compete and even win something. There is free limited version and paid PRO version. All user data is synced with profile on <u>www.endomondo.com</u>. However, Endomondo offers no API at the moment.

## My Tracks

My Tracks<sup>183</sup> records path, speed, distance, and elevation while walking, running, biking, or doing anything else outdoors. Is allows annotating the path and includes voice announcements. App uses GPS sensor and works with third-party devices, including:

- Zephyr HxM Bluetooth heart rate monitor
- Polar WearLink Bluetooth heart rate monitor
- ANT+ heart rate and speed distance monitors

Since My Tracks is made by Google, this app syncs with Google Drive, allows exporting tracks to Google Maps Engine, Google Spreadsheets or external storage. It also offers API<sup>184</sup> for third party applications to access MyTracks data. The app is free of charge.

<sup>&</sup>lt;sup>182</sup> <u>https://play.google.com/store/apps/details?id=com.endomondo.android</u>

<sup>&</sup>lt;sup>183</sup> <u>https://play.google.com/store/apps/details?id=com.google.android.maps.mytracks</u>

<sup>&</sup>lt;sup>184</sup> <u>https://code.google.com/p/mytracks/wiki/MyTracksApi</u>



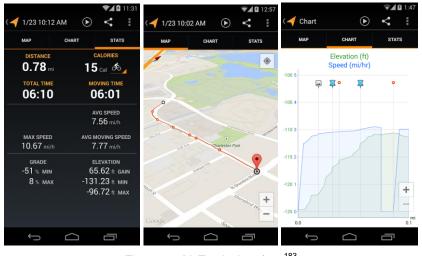


Figure 56. MyTracks interface<sup>183</sup>

# RunKeeper - GPS Track Run Walk

Runkeeper<sup>185</sup> allows tracking pace, cycling speed, route distance, elevation and calorie burn of walks, bike rides and other outdoor workouts using GPS in Android phone. The app also gives audio updates, and integrates with phone's music app.



Figure 57. RunKeeper interface<sup>185</sup>

Runkeeper syncs with the best fitness apps and devices used for nutrition, sleep monitoring, weight, step tracking, calorie counting and getting rewards, including:

- Polar Heart Rate monitor
- Pebble smart watch
- Samsung Galaxy Gear smart watch
- MyFitnessPal calorie tracking app
- Fitbit activity monitoring devices
- Garmin Forerunner GPS watches and Garmin Connect
- Withings wifi scales

<sup>&</sup>lt;sup>185</sup> <u>https://play.google.com/store/apps/details?id=com.fitnesskeeper.runkeeper.pro</u>



- Sleep Cycle app
- Jawbone Up
- GymPact
- Gym Hero
- various pedometers

The app itself is free of charge and offers with free of charge basic account, but there is paid account version called Runkeeper Elite. Runkeeper offers HealthGraph API<sup>186</sup>, which uses OAuth 2.0 authorization protocol.

### Runtastic Running & Fitness

Runtastic<sup>187</sup> uses GPS to map and track sports and fitness activities, such as running, jogging, biking & walking. It tracks time, distance, elevation and calories and allows using popular music apps within itself. Audio feedback, goals, mapping of training sessions are also available. The app can be controlled with Android Wear. Workouts can be saved to Runtastic.com. Some features are limited in the free version of Runtastic, but there is paid PRO version. However, Runtastic offers no API.

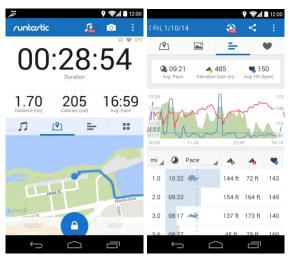


Figure 58. Runtastic Running & Fittness interface<sup>187</sup>

### 2.5.3.2. Daily activity tracking

### Samsung S Health

Samsung's latest Galaxy S5 comes with a built-in heart rate monitor and an installed personal wellness app called S Health<sup>188</sup> to help to keep track of health and fitness. The S Health app covers many aspects of wellness — it includes a nutrition diary, a pedometer and an exercise section for running, cycling and hiking.

### Sensorfit Activity Tracker

Sensorfit<sup>189</sup> shows daily physical activity and calories burned during the day, the last week or this year. App is free of charge for 1 week and then it costs \$0,99 per month. There are no information on compatibility with other apps, devices or any kind of API.

<sup>&</sup>lt;sup>186</sup> <u>http://developer.runkeeper.com/healthgraph/getting-started</u>

<sup>&</sup>lt;sup>187</sup> <u>https://play.google.com/store/apps/details?id=com.runtastic.android</u>

<sup>&</sup>lt;sup>188</sup> <u>http://www.livescience.com/45292-galaxy-s5-health-app-review.html</u>

<sup>&</sup>lt;sup>189</sup> <u>https://play.google.com/store/apps/details?id=com.sensorfit.easyfit.app</u>





Figure 59. Sensorfit Activity Tracker interface<sup>189</sup>

#### Moves

Moves<sup>190</sup> automatically tracks everyday life and exercise. It records daily walking, cycling and running, recognizes places, visualizes day in timeline, counts steps and is open to other apps. Moves offers open API<sup>191</sup> using OAuth 2.0 authorization protocol.

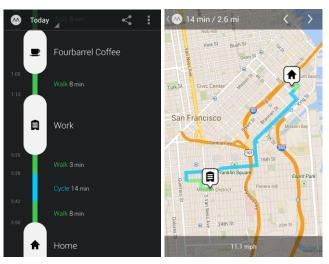


Figure 60. Moves interface<sup>190</sup>

### 2.5.3.3. Step counting

Step counting is one of the most popular methods for daily activity tracking. Since most of the new smartphones have embedded accelerometers, it is not a hard task for developers to create step counting app based on acceleration readings. There are many pedometer type apps on Google Play – when using keywords such as "pedometer" or "step counter" one can get more than 30 relevant results. Even more, in the latest Android (4.4) there comes built in API support for step counter sensors (see more in 0). Therefore we decided to review only one pedometer app as an example – Runtastic Pedometer. The app itself was chosen because of good user reviews and popularity.

<sup>&</sup>lt;sup>190</sup> <u>https://play.google.com/store/apps/details?id=com.protogeo.moves</u>

<sup>&</sup>lt;sup>191</sup> <u>https://dev.moves-app.com/</u>



#### Runtastic Pedometer

Runtastic Pedometer<sup>192</sup> automatically records steps, calculates speed, distance, step frequency. It integrates with MyFitnessPal account and is compatible with Runtastic.com. Lite version of the app is free of charge, but there is paid PRO version.

4	A	4:00		<b>afi 🗎 4:00</b>
runtartic Pedometer	go Pro 🎜	:	<b>runtartic</b> Pedometer	<
		GO PRO	P FREQUENCY ZONES SUMMARY	ADDITIONAL INFO 3/23/13 3:07 PM
3072 steps	00:23:30		1376 steps	01:34:41 duration
A 3.2 MPH SPEED	1.43 мі distance		Distance	0.63 mi
CALORIES		PRO	Avg. Step Frequency	14s pro
			Avg. Pace	150:17 min/mi
3072	steps		Avg. Speed	0.4 mph
			le Calories	C PRO
PAUSE	STOP		Pause	00:09:25

Figure 61. Runtastic pedometer interface<sup>192</sup>

### Step Counter sensor on Android API

Android KitKat OS version 4.4<sup>193</sup> offers some additional features. One of them is support for two new composite sensors – step detector and step counter — that allows tracking steps when the user is walking, running, or climbing stairs. These new sensors are implemented in hardware for low power consumption. The step detector analyses accelerometer input to recognize when the user has taken a step, then triggers an event with each step. The step counter tracks the total number of steps since the last device reboot and triggers an event with each change in the step count. Because the logic and sensor management is built into the platform and underlying hardware, there is no need to maintain detection algorithms in the app. For now, step detector and counter sensors are available on Nexus 5, Samsung Galaxy S4 and S5. Moves and Runtastic Pedometer are using the hardware step-detector. There is full API description<sup>194</sup> for these sensors.

Recently (as of June 25 2014) Google Inc. announced an open platform of API's that lets users control their fitness data<sup>195</sup>. New APIs will make building fitness apps and devices easier. It will include: Sensors API (for sensor discovery), Recording API (for connecting app and devices to Google Fit), History API (for accessing and editing the user's fitness history). The Google Fit SDK will be available in fall 2014.

#### 2.5.4. Summary

Some of the reviewed devices can be referred to as suitable for daily activity tracking and the other ones more suitable for workout tracking. Therefore, the latter ones, such as Adidas devices, are not recommended. The most interesting and the most suitable device seems to be Fitbit One, because of its additional altimeter sensor and climbed stairs counting feature. Battery life is 2-3 times longer than Fitbit Flex, which costs the same. On the other hand, the wearing site differs, hence it should be considered in terms of comfort and unobtrusiveness. Medisana VIFIT Connect is another interesting candidate since it also employs altimeter sensor, even though it does not count stairs. It is the cheapest one available (in Lithuania).

<sup>&</sup>lt;sup>192</sup> <u>https://play.google.com/store/apps/details?id=com.runtastic.android.pedometer.lite</u>

<sup>&</sup>lt;sup>193</sup> <u>https://developer.android.com/about/versions/kitkat.html</u>

<sup>&</sup>lt;sup>194</sup> http://developer.android.com/about/versions/android-4.4.html#UserInput

<sup>&</sup>lt;sup>195</sup> The Google Fit SDK,<u>https://developers.google.com/fit/</u>



The last device worth considering should be Samsung GEAR Live. It comes from the completely new level, comparing to Fitbit and Medisana devices. On one hand, it is smart watch compatible with Android smartphones, on the other hand, it is activity tracker employing standard inertial and heart rate sensors. This smart watch is also very interesting because of the Android Wear operating system, which has full SDK and allows developers accessing the sensors. The main problems with this device are high price, not clear availability in Europe and short battery life.

	Table 7. Summary of devices for physical activity and sleep monitoring.						
Device	Sensors and actuators	Parameters	Battery	Connecti- vity	Android/ iOS compati bility	ΑΡΙ	Price
Fitbit One	Accelerometer, altimeter, vibration motor	Steps, distance travelled, calories burned, stairs climbed, sleep quality	10-14 days	Bluetooth 4.0 LE	Both	Cloud based	\$99,95, 100 €, 350 Lt
Fitbit Flex	Accelerometer, vibration motor	Steps, distance travelled, calories burned, sleep quality	~5 days	Bluetooth 4.0 LE	Both	Cloud based	\$99,95, 100 €, 350 Lt
iHealth tracker	Accelerometer, vibration motor	Steps, calories burned, travelled distance, hours slept, times of waking up, sleep efficiency score	~7 days	Bluetooth 4.0 LE	Both	Cloud based	\$59,95, 250 Lt
Medisana VIFIT Connect	Accelerometer, altimeter	Steps, calories burned, distance walked, duration of the activity, sleep duration, sleep quality	5-7 days	Bluetooth 4.0 LE	Both	Cloud based	69 €, 216 Lt
Scosche RHYTHM +	Optical heart rate	Heart rate	8 hours	Bluetooth 4.0 LE, ANT+	Both	No info	\$99,95, 99 €
Samsung GEAR Live	Accelerometer, optical heart rate	Heart rate, steps	1 day	Bluetooth 4.0 LE	Android	Android Wear SKD	\$199, £169
Adidas SmartRun	Accelerometer, optical heart rate, GPS	Speed, location, path, heart rate.	8 hours	Bluetooth 4.0 LE, USB	Android	None, in future plans.	\$399, £350
Adidas Fit Smart	Accelerometer, optical heart rate	Pace, calories, time, distance, heart rate	5 hours	Bluetooth 4.0	Both	None, might be Google Fit SDK.	\$199, £199

Google My Tracks app is clearly the best for workout tracking, due to being completely free of charge and offering full API. Another app worth considering might be Runkeeper GPS. While it does offer API called HealthGraph and the app is free itself, there are paid account subscription for \$9.99 per month. While talking about daily activity tracking app, it seems that Moves does not have any competitor. It is free, offers API via OAuth, tracks more than just steps and allows manually mapping one's daily activity. On the other hand, custom made pedometer, using step counter from Android API and compatible smartphone is also worth considering

Table 8. Summary of apps for physical activity and sleep monitoring.					
AppSensors usedParametersAPIPrice		Price			
Endomondo Tracker	Sports	GPS	Duration, speed,	None	Free limited version, 12,99 Lt (~\$5) for PRO version



		distance, calories		
My Tracks		Path, speed, distance, elevation	Full	Free
Runkeeper – GPS Track Run Walk		Pace, cycling speed, distance, elevation, calorie burn	Full, HealthGraph, via OAuth 2.0	Free app, paid account subscription \$9,99/month
Runtastic Running & Fitness		Time, distance, elevation, calories	None	Free limited version, 8,6 Lt (~\$3,4) for PRO version
S Health		Steps	None	Free, comes preinstalled in Samsung Galaxy S5
Sensorfit Activity Tracker		Calories	None	1 week free, later \$0,99
Moves	Accelerometer	Steps, duration	Full, via OAuth 2.0	Free
Runtastic Pedometer		Steps	None	Free limited version, 4,99 Lt (~\$2) for PRO version
Step Counter on Android 4.4		Steps	Full, Android API	Free

# 2.6. Cloud based ecosystems for personal health monitoring

Ecosystems are mobile personal healthcare products such as blood pressure monitor, body composition scales, activity and sleep trackers, pulse oximeters, glucometers and etc. that connect (wirelessly) to the dedicated virtual computing infrastructure - cloud. These innovative companies are good examples of ecosystems providers: iHealth Labs Inc., Medisana AG, Withings. The short description below summarizes several cloud based ecosystems for personal health monitoring.

### 2.6.1. iHealth Lab Inc.

iHealth Lab<sup>196</sup>Inc. (later iHealth)<sup>197</sup> is USA company providing 6 wireless devices that can be synced with the iHealth Lab cloud: two types of blood pressure monitors, physical activity and sleep tracker, body analysis scale, pulse oximeter and glucose monitoring system.

iHealth Lab devices are relevant to CARRE project as they could be used to measure 22 different health parameters (including body composition parameters such as body fat, body muscle and total body water) identified in Domain analysis as important biomarkers. All devices have CE label, conform to standards, are available in Europe and relatively inexpensive (see Figure 62).

The accuracies are declared for all devices: body weight ±1%, blood pressure ±3 mmHg, pulse oximeter 0-99%, ±2%. There is no definition for activity monitor and blood glucose accuracy is not specified. We have performed preliminary testing of blood pressure monitor by using patient simulators having blood pressure simulation feature AccuSimBP Handheld NIBP Simulator (accuracy: +/- 0.5 mmHg) and Fluke Prosim 8 (accuracy: +/- 0.5 mmHg). The preliminary results showed positive bias (5 mmHg) in systolic measurements, negative bias (-5 mmHg) in diastolic measurements. Precision was estimated as the standard deviation of repeated measurements of differences between measured blood pressure and reference. It was found that precision estimate is less than 2.5mm Hg. We compared these estimates to popular blood pressure monitor MicrolifeBP A100 and got similar results. More thorough testing and investigation of other devices (body scales, physical activity monitor) is desirable and is planned.

<sup>&</sup>lt;sup>196</sup> <u>http://www.ihealthlabs.com/</u>

<sup>&</sup>lt;sup>197</sup> <u>http://developer.ihealthlabs.com/index.htm</u>



All the devices except one use Bluetooth for connection to smart phone. The body composition scales use WiFi for sending data to the cloud. This is especially convenient as it frees the user from looking for smart phone in the morning when measurements are to be done. All devices connect to Android and iOS smart phones via dedicated free apps. One disadvantage – 3 apps are needed to connect to all iHealth Lab devices: iHealth SpO2 (for pulse oximeter), iHealthGluco-Smart (for glucose measuring), iHealthMyVitals (for all other parameters).

It is expected that three more devices will ship in the second half of 2014: a blood pressure monitoring vest, ECG device that sticks to the wearer's chest, and a wrist worn pulse oximeter device<sup>198</sup>. Blood pressure monitor will provide 24-hour monitoring of blood pressure with monitoring periodicity 15 minutes, 30 minutes, 45 minutes, every hour, or every two hours. All-day and all-night measurements are helpful in better understanding nocturnal hypertension, "white-coat" hypertension, and titration of antihypertensive medications. ECG device will stick to the user's chest by using disposable, adhesive patch and will be worn under clothing. The device will be used for detecting arrhythmia or abnormal heart rate. Bluetooth 4.0 BLE will be used for data transmission. It will be able to store 72 hours of data. It is not clear yet about compatibility with Android operating system. The third device, wrist worn pulsoximeter, continuously monitors blood oxygen saturation and pulse rate via a fingertip sensor that connects to a wristband, which has its own dedicated screen. Such monitoring could be useful for detection of obstructive sleep apnoea syndrome. It also has Bluetooth 4.0 BLE and works with iOS and some Android devices. It will be able to store about 1,000 hours of data.



Figure 62. iHealth Lab Inc. ecosystem (adopted from<sup>196</sup>)

There are projects, which already take advantage of open iHealth Lab platform, for example, "Health eHeart Study"<sup>199</sup>. The project is run by University of California with the goal to gather more data about heart health from more people than any research study has done before and to develop strategies to prevent and treat all aspects of heart disease. The project has chosen to aggregate data from Fitbit physical activity device, iHealth Lab devices and Withings ecosystems devices.

# 2.6.2. Withings

Withings is a French private company providing 3 devices: body composition scales, blood pressure monitor and activity tracker with pulse oximetry capability<sup>200</sup>. Body composition scales can measure weight, BMI, fat,

<sup>&</sup>lt;sup>198</sup> <u>http://mobihealthnews.com/28547/ihealth-unveils-wearable-ecg-pulse-ox-bp-devices/</u>

<sup>&</sup>lt;sup>199</sup> http://www.health-eheartstudy.org/study

<sup>&</sup>lt;sup>200</sup> <u>http://www.withings.com/eu/</u>



heart rate, also environment variables – air quality and air temperature. However, these scales are not able to estimate total body water. This is drawback for our application. Withings API documentation is available at<sup>201</sup>.



Figure 63. Withings ecosystem (adopted from<sup>200</sup>)

# 2.6.3. Medisana AG



Figure 64. Medisana ecosystem (adopted from<sup>202</sup>)

Medisana AG (later Medisana) is a German company providing 4 wireless monitoring devices (Figure 64) that can be synced with the Medisana's "VitaDock Online" cloud: 3 different types of body composition

<sup>&</sup>lt;sup>201</sup> <u>http://oauth.withings.com/api</u>



scales, 3 blood pressure monitors (2 upper arm, 1 wrist worn), 1 physical activity / sleep quality tracker, 1 blood glucose meter<sup>202</sup>.

The Medisana's devices can measure 20 different health parameters (including body composition parameters such as body fat, body muscle and total body water) identified in the Domain analysis as the important biomarkers. All the devices have CE label, conform to standards, are available in Europe and are relatively inexpensive (see Figure 64).

The accuracies are declared for all devices: body weight  $\pm 1\%$ , blood pressure  $\pm 3$  mmHg. Preliminary comparison tests with iHealth Lab devices show slight differences in measurements.

Medisana API documentation is available at<sup>203</sup>.

### 2.6.4. Samsung Simband health-tracking wristwatch and S.A.M.I ecosystem

Samsung Simband<sup>204</sup> (Figure 65) was announced recently (May, 2014). It is not a product but it is an open reference design. It features multimodal sensors for optical, electrical and physical methods of collecting real-time health data. Bioimpedance sensors can measure blood flow and body fat noninvasively. Photoplethysmogram (PPG) sensors are being designed to calculate heart rate and blood pressure. These PPG sensors use red and green lights at various wavelengths, which provide for better accuracy in heart rate estimation. Electrocardiogram signal (ECG) is captured with two electrodes– one in the band and another in the clasp. ECG is measured only when touching with non-watch hand to the clasp. Simband measures skin temperature and galvanic skin response, which could provide clues about core temperature and stress levels.

Very little was announced about specifications, mainly about the processor - 1GHz dual-core ARM A7- and connectivity -WiFi and Bluetooth. Wireless battery charging was mentioned as well.



Figure 65. Samsung Simband wristwatch (adopted from<sup>205</sup> and <sup>206</sup>)

Samsung invites the developer community to join in building ecosystem of new smart health apps and services. Open SDK was promised later this year.

Big advantage of this platform – unprecedented integration of so many sensors into convenient to wear device, wristwatch, and openness to developers. This device could be very useful for the project CARRE. However, functions, quality of the signals, quality of the hardware should be investigated.

Samsung's cloud based ecosystem Samsung Architecture Multimodal Interactions (S.A.M.I<sup>207</sup>) also was announced recently. S.A.M.I. will be a data broker that will enable wearable devices like those based on Simband to upload information to the cloud. The open nature of S.A.M.I. and its APIs will allow for easy aggregation of the data from a variety of devices. It will act as a platform, which sits between devices that collect data, and algorithms in the cloud that analyse that data. From there, developers can access the data and leverage it to create new applications. The S.A.M.I. will allow visualization of data in a user's different contexts: calendar, location, behaviour, environment and more. Basic rule engines, machine learning and algorithms in S.A.M.I. will help process the data and perform analysis.

<sup>&</sup>lt;sup>202</sup> <u>http://www.medisana.com/en/Mobile+Health/</u>

<sup>&</sup>lt;sup>203</sup> <u>http://www.vitadock.com/api/for-developers.html</u>

<sup>&</sup>lt;sup>204</sup> http://www.samsung.com/us/globalinnovation/innovation\_areas/

<sup>&</sup>lt;sup>205</sup> http://www.bbc.com/news/technology-27612110

<sup>&</sup>lt;sup>206</sup> http://www.pcmag.com/article2/0,2817,2458663,00.asp

<sup>&</sup>lt;sup>207</sup> http://www.samsung.com/us/globalinnovation/pdf/Samsung\_SAMI\_Backgrounder.pdf



Privacy is warranted - it is the property of the person creating the data: "S.A.M.I. is designed to store and secure users' data and acts as a personal data bank. Just as a bank doesn't own individual's money, Samsung doesn't own personal health data, nor does Samsung share data without an individual's consent"<sup>208</sup>. S.A.M.I looks very promising but we need to wait when it is available for developers.

# 2.7. Possible future research directions and developments

The analysis in this report demonstrates availability and huge diversity of commercial personal health devices. However, a close inspection of available devices and some identified observables for project CARRE application (CRS monitoring) in "D.2.2. Functional Requirements & CARRE Information Model" suggest that some suitable devices does not exist. The examples of unsuitable devices: they are expensive clinical devices (e.g. body hydration, sleep apnea, arrhythmia (Holter) monitors), they need additional operator (e.g. tonometers for pulse wave velocity (PWV) measurement), they do not measure needed observables (e.g. physical activity units METS), they do not have alert functionality if too long physical inactivity. Thus, it is worth to investigate possibilities to develop/adapt new sensors systems:

- 1. CARRE wristwatch for wireless *continuous* monitoring of:
  - a. Physical activity for physical exercise, Metabolic Equivalent in METS;
  - b. Sleep apnea (Apnea hypopnea index);
  - c. Arrhythmia (Atrial fibrillation);
  - d. Stress.
- 2. CARRE weight scales for wireless *intermittent* monitoring of:
  - a. TBW, ICW, ECW, BIVA parameters for fluid balance estimation;
  - b. ECG and heart rate;
  - c. Impedance cardiography based central pulse wave velocity (PWV) and arterial stiffness estimation.

The main ideas under CARRE wristwatch are: fusion of accelerometer and pulse rate sensors for more accurate physical activity estimation under dynamic (e.g. walking, running) and static (e.g. cycling) conditions, SpO2 / pulse rate sleep apnea detection, silent arrhythmia detection during the night, controlled breath based biofeedback for stress lowering. The main sensors in this device – photoplethysmography (PPG) and 3D accelerometer.

CARRE weight scales could solve the issues of personal intermittent hydration and operator less central PWV observables monitoring.

# 2.8. Ethical, privacy policy and data security issues

### 2.8.1. Ethical and privacy policy

All analysed cloud based ecosystems of devices for personal health monitoring (see chapter 2.6) have privacy policies<sup>209,210,211,212</sup>. As an example Fitbit Inc. includes these chapters in its privacy policy: what personal Information they collect, how they use collected personal information, disclosure to third parties, use of aggregated anonymous user data, cookies and other technology, information elected to share with others, third party products or services offered through the Fitbit site, rights to delete data, data security

<sup>&</sup>lt;sup>208</sup> <u>http://www.samsung.com/us/globalinnovation/media/</u>

<sup>&</sup>lt;sup>209</sup> <u>http://developer.ihealthlabs.com/dev\_business\_39.htm</u>

<sup>&</sup>lt;sup>210</sup> <u>http://www.withings.com/eu/privacy-terms</u>

<sup>&</sup>lt;sup>211</sup> <u>https://cloud.vitadock.com/privacy.html?lang=en</u>

<sup>&</sup>lt;sup>212</sup> <u>http://www.fitbit.com/privacy</u>



measures, privacy complaints by European Union citizens (Fitbit complies with the U.S. - EU Safe Harbor Framework<sup>213</sup>), user responsibility for maintaining the confidentiality of the login ID and password.

### 2.8.2. Data security

Data security in CARRE accounts can be maintained and protected from unauthorized access by the use of the combination of the authentication procedures, encryption techniques and server firewall barriers.

The communication with data providers (the cloud-based ecosystems for personal health monitoring) goes through standard security protocols. OAuth 1.0(a) and OAuth 2.0 are the most adopted and applied open security standards for authorization. OAuth protocols specify a process for resource owners to authorize third-party access to their server resources without sharing their credentials (username and password).

Protocols OAuth 1.0(a) and OAuth 2.0 are not backwards compatible. Thus they should be implemented both in CARRE system. The usage of OAuth protocol version by relevant data providers API's is provided in table below:

Table 9. Summary of data service providers and OAuth protocol version.			
No.	. Service provider Protocol version		
1	iHealth Lab Inc.	OAuth 2.0	
2	Withings	OAuth 1.0	
3	Medisana AG	OAuth 1.0	
4	Fitbit Inc.	OAuth 1.0	

As can be seen in Table 9, different biomedical data monitoring service providers implement their own data security measures and have their own APIs. Access to the data may be accomplished using one of the two OAuth protocol versions (1.0 and 2.0). For example, iHealth Lab and Medisana use different OAuth versions, 2.0 and 1.0 respectively. Service providers (owners of cloud based ecosystems for personal health monitoring) offer developers options to gain access to their data servers via open API's. In order to gain access to the data servers, the developers have to create the application in the service provider web site. The application must contain the URL (Uniform Resource Locator) of the third party server (e.g. CARRE server) where the data from the data provider will be downloaded. When the application form is created, service provider sends special access credentials (codes), which will be used to connect to its data servers. In order to connect to the data servers of various service providers, CARRE system must contain access implementations by following the requirements of each service provider APIs. There is no unified and standardizes access to various service providers, however some components e.g. from OAuth implementations can be mutually used to access different data servers. For example, if CARRE system user is monitored e.g. by Medisana AG products, this user must create an account in the Medisana's web page https://cloud.vitadock.com/ . When user connects to the CARRE system, he / she is prompted to choose its service provider, e.g. by pressing button or choosing from the list of available services and will be redirected to the Medisana login page. After typing his username (or email) and password, he will be redirected back to the CARRE system and his personal data will be downloaded to the CARRE server.

The created passwords after registration to the CARRE service must be stored in encrypted fashion on the CARRE system. All servers must be protected from viruses by antivirus software with regular frequent updates of the virus signatures. The servers that will store CARRE data must be behind the secure firewall that would not allow unauthorized access to any research data server. The CARRE database must be backed up to another secure file server or another storage media, which could be stored off-site and would allow for system and data recovery even in the event that server room is destroyed.

<sup>&</sup>lt;sup>213</sup> <u>http://www.export.gov/safeharbor/</u>



# 3. Sources of personalized medical information

# 3.1. Types of electronic health records that could be harvested

Electronic Health Record (EHR) is a term describing a medical record stored in an electronic medium. ISO/TR 20514 defines an EHR as "a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely and accessible by multiple authorized users. It has a standardized or commonly agreed logical information model, which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent and prospective"<sup>214</sup>. Although in common usage this term is used interchangeably with another relevant term, Electronic Medical Record (EMR), there are key differences between the two. While EMR is a legal record created by healthcare institutions, EHR is a record more oriented towards medical information follows the patient<sup>215</sup>. The availability of EMRs, although costly, has been shown to be effective and beneficial both for the healthcare professionals and the patients<sup>216</sup>.

Personal Health Record (PHR) – is a type of electronic health record with one key difference – it is a medical data repository created and maintained by a patient her/himself.

Personal health record systems are more than just static repositories for patient data; they combine data, knowledge, and software tools, which help patients to become active participants in their own care<sup>217</sup>. It is important to note that, while it both encourages and empowers patients to create health profile and put all healthcare information together, due to the lack of relevant knowledge patients may misinterpret their medical records and they could be of poor quality<sup>218, 219</sup>. On the other hand, PHR could lead to a more complete medical records for patients moving to locations where their EHRs/EMRs cannot be accessed, e.g. outside the country of residence.

There are several historical, regional and contextual variants denoting EHR<sup>220</sup>:

- Electronic Medical Record (EMR) in North America and Japan patient focused clinical information from one functional medical unit. Though regarded as an outdated term, is described as interchangeable with EHR;
- Electronic Patient Record (EPR) used by the English National Health Service;
- Computerized Patient Record (CPR) used in the US, denotes either EPR or EMR.

<sup>&</sup>lt;sup>214</sup> ISO – TC 215, ISO/TR 20514, Health informatics – Electronic health record – Definition, scope and context, Geneva 2005.

<sup>&</sup>lt;sup>215</sup> Spasov G, Petrova G. Electronic Health Records -- Basic Models and Specifics. Annual Journal Of Electronics [serial online]. 2011 June; 5(2):64-67. Available from: Academic Search Complete, Ipswich, MA. (Last accessed: 07/07/2014)

<sup>&</sup>lt;sup>216</sup> Tierney W, Zafar A (2002) EMRs: An Introductory Tutorial, Available at <u>http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS 0 251 0 0 18/EMR%20Talk.ppt</u>

<sup>&</sup>lt;sup>217</sup> Paul C. Tang, Joan S. Ash, David W. Bates, J. Marc Overhage and Daniel Z. Sands. Personal Health Records: Definitions, Benefits, and Strategies for Overcoming Barriers to Adoption. J Am Med Inform Assoc. 2006; 13(2): 121– 126.

<sup>&</sup>lt;sup>218</sup> Spasov G, Petrova G. Electronic Health Records -- Basic Models and Specifics. Annual Journal Of Electronics [serial online]. June 2011;5(2):64-67. Available from: Academic Search Complete, Ipswich, MA. (Last accessed: 07/07/2014)

<sup>&</sup>lt;sup>219</sup> Roberts J. Personal electronic health records: from biomedical research to people's health. Informatics In Primary Care [serial online]. 2009 December; 17(4):255-260. Available from: Academic Search Complete, Ipswich, MA. (Last accessed: 07/07/2014)

<sup>&</sup>lt;sup>220</sup> C.U. Lehmann et al. (eds.), Pediatric Informatics: Computer Applications in Child Health, Springer Science+Business Media, 2009, ISBN: 978-0-387-76445-0.



# 3.2. Interoperability and record standardization issues

It is of no surprise that the form and content of any electronic record relies heavily upon specific implementation of a solution, and PHR is no exception. Interoperability is both of great importance and spanning over many domains including organizational, semantic, syntax and technical<sup>221</sup>.

The need for standardized medical records arises from the need for the health care professionals to deliver a complex and knowledge-intensive health care for their patients and the exchange of said information between and within care teams unambiguously and accurately<sup>222</sup>. ICD10 could be an example of an established standard for unambiguous description of a clinical diagnosis. Unfortunately, EHRs can be complex both in their contents and hierarchy. It is of utmost importance that interpretation of complex is rigorous, unambiguous and certain.

Several overlapping standards to improve clinical content and structure and implementation have been developed, such as:

- SNOMED-CT, a comprehensive reference terminology allowing healthcare providers to record medical data accurately and unambiguously<sup>223</sup>,
- Health Informatics Service Architecture (HISA), which provides a formal standard for a Service Oriented Architecture (SOA), specific for the requirements of health services, based on the principles of Open Distributed Processing<sup>224</sup>;
- ISO technical committee ISO/TC 215, has also been active since 1998, having published some 126 ISO standards related to health informatics<sup>225</sup>,
- international standard developing organization Health Level Seven International (HL7), active since 1987, has developed a large number of standards and standard practices spanning various aspects of EHRs, ranging from recommended best practices to access control<sup>226</sup>,
- OpenEHR, an open standard focusing mostly on the management and storage, retrieval and exchange of health data, has been established by the openEHR Foundation<sup>227</sup>.

# 3.3. Technical plausibility of PHR data aggregation

There are some problems with medical record data aggregation, which must be weighted when considering a technical solution, first of which is that healthcare data may exist in multiple systems, each with different capabilities. Thus data aggregator solution should be solution-agnostic, i.e. uncoupled to another solution, generic enough to accept data from variety of sources. The aggregator should also remain adaptable and current. This could be achieved by using Health IT standards both for format (such as HL7) and coding (Such as SNOMED-CT)<sup>228</sup>. Another problem is data normalization – aggregator input data may be duplicated because of human error, variations in name, name changes because of marriage, et cetera. Data could be

<sup>&</sup>lt;sup>221</sup> Ibid.

<sup>&</sup>lt;sup>222</sup> Kalra, Dipak. Electronic health record standards. 2006: 136-144.

<sup>&</sup>lt;sup>223</sup> Lee D, Lau F, Hue Q.A method for encoding clinical datasets with SNOMED CT. BMC Medical Informatics & Decision Making [serial online]. January 2010;10(1):53-64. Available from: Academic Search Complete, Ipswich, MA. (Last accessed: 08/07/2014)

<sup>&</sup>lt;sup>224</sup> Klein, Gunnar. Sottile, Pier Angelo.Endsleff, Frederik. (2007) Another HISA - The new standard: Health Informatics -Service Architecture, Studies in Health Technology and Informatics, 129(Pt 1):478-82.

<sup>&</sup>lt;sup>225</sup> International Standards Organization.Standards catalogue (ISO/TC215 - Health informatics). <u>http://www.iso.org/iso/home/store/catalogue\_tc/catalogue\_tc browse.htm?commid=54960&published=on</u>. (Last accessed: 07/07/2014)

<sup>&</sup>lt;sup>226</sup> <u>http://www.hl7.org/implement/standards/product\_matrix.cfm?ref=nav</u> (Last accessed: 07/07/2014)

<sup>&</sup>lt;sup>227</sup> http://www.openehr.org (Last accessed: 30/07/2014)

<sup>&</sup>lt;sup>228</sup> Wellcentive. Data Aggregation and Normalization for Population Health Management. <u>http://www.wellcentive.com/data-aggregation-and-normalization/</u>. (Last accessed: 15/07/2014)



normalized either manually, or using an Enterprise Master Patient Index (EMPI/MPI) solution<sup>229</sup>. It also needs to have methods to access and present aggregated data in a number of ways.

Considering these requirements, it seems quite possible to design an aggregator which uses HL7 FHIR standard for messaging and OpenEHR as a repository and query engine, acting as a RESTful service (provided by HL7 FHIR), exposing a web endpoint for various HISes, which could also use HL7 FHIR as an aggregator client to send data. An EMPI/MPI solution such as OpenEMPI<sup>230</sup>could be used to provide data normalcy and consistency.

# 3.4. PHR selection criteria

IN CARRE, sources of PHR data selection criteria were considered:

- popularity
- API
- freely available
- standards
- EU project results uptake

# 3.5. Currently available sources of PHR data

There is a number of commercial and closed PHR systems including (but not limited to):

- Microsoft HealthVault<sup>231</sup>
- WebMD PHR<sup>232</sup>
- Epic Systems' MyChart<sup>233</sup>
- The Patient Portal, from Cerner Corp.<sup>234</sup>

Unfortunately, harvesting data from these systems is unlikely at this time (apart from HealthVault, see below), as negotiations with their respective owners would be needed at least, not to mention other legal and ethical aspects concerning medical data stored on these systems.

Vilnius University Hospital Santariškių Klinikos (VULSK) also has developed (or taken part in developing) a few PHR repositories - Internet Patient History  $(IPK)^{235}$  and VivaPort – a multilingual personal health portal<sup>236</sup>.

### HealthVault

HealthVault site is designed to be an online, encrypted vault, where users can store and manage their health records also the site serve as a repository for health-related articles and other information<sup>237</sup>. It is a free service and it offers<sup>238</sup>:

<sup>&</sup>lt;sup>229</sup> Ibid.

<sup>&</sup>lt;sup>230</sup> Open Enterprise Master Patient Index. OpenEnterpriseMasterPatientIndex. <u>http://www.openempi.org/</u>. (Last accessed: 14/07/2014)

<sup>&</sup>lt;sup>231</sup> Microsoft HealthVault. HealthVault. <u>https://www.healthvault.com/</u>. (Last accessed: 29/07/2014)

<sup>&</sup>lt;sup>232</sup> WebMD. Personal health record. <u>http://www.webmd.com/phr</u>. (Last accessed: 15/07/2014)

<sup>&</sup>lt;sup>233</sup> EpicSystems. Mobile Applications and Portals. <u>https://www.epic.com/software-phr.php</u>. (Last accessed:15/07/2014).

<sup>&</sup>lt;sup>234</sup> Cerner. PatientPortal. <u>https://www.cerner.com/solutions/Physician\_Practice/Patient\_Portal/</u>. (Last accessed: 15/07/2014)

<sup>&</sup>lt;sup>235</sup> IPK. Internetinė Paciento Kortelė. <u>https://viva.santa.lt/ipk/</u>. (Last accessed:15/07/2014)

<sup>&</sup>lt;sup>236</sup> VivaPort. MultilingualPersonalHealthPortal. <u>https://vivaport.eu/</u>. (Last accessed: 15/07/2014)



- A Microsoft platform for health information and innovation: developer engagement and tools, durable, supported interfaces, cross-platform commitment, high service availability and redundancy, longterm investment, enterprise footprint, continuous platform improvement, international availability.
- Built-in functionality for privacy, security, and data provenance. Access to a record is through a HealthVault account. Authorization of the account can be through <u>Windows Live ID</u>, <u>Facebook</u> or a limited set of <u>OpenID</u> providers<sup>239</sup>.
- Vendor neutrality: platform exposes an XML-over-HTTP interface to web and mobile applications.
- A flexible health data type system that supports data interoperability. The HealthVault data type system supports industry standards. Where no standards exist, the HealthVault team uses a robust, community-informed data type design process.
- Cloud service and storage of account-holders' personal health records.
- Device connectivity, including: weight scales; blood pressure monitors; blood glucose monitors; pedometers and activity monitors; heart rate monitors; pulse oximeters.

#### VivaPort

VivaPort portal was developed during the implementation of EU Baltic Sea Region Programme 2007-2013 project "ICT for Health". The usage of the portal and test scenarios allow pilot implementation in the real environment and also enable to compare the experiences and find best possible ways to solve the crossborder problems of health communication in Baltic Sea Region. Implemented functionalities of the portal substantially increase the safety of travelling patients with health risks, ensuring the access to vital information wherever they are, thus diminishing risks during health events. The portal concept is favourable for the promotion of eHealth and empowerment of patients to take more care about their own health, to change a lifestyle and be aware about their health status and long-term trends.

Innovative features offered by the portal:

- Concept of multi-language portal for the cross-border travelling persons having health risks which has no real working prototypes on the market
- New software tools for the multi-language translation of portal interface, medical records and classifiers allowing working online
- Implementation of the portal registration by the use of mobile phone and SMS messages
- Implemented functionality to manually enter health parameters and upload health monitoring data by using smartphone application, possibility to observe time dependences and trends
- Portal architecture and technological tools enable the future evolvement of the portal in terms of new countries/languages involved, integration with eHealth systems and EU project epSOS developments
- Elaborated usability test for evaluation and research of portal acceptability and patient's readiness.

#### MyHealthAvatar

The MyHealthAvatar is a promising 7<sup>th</sup> Framework Programme of European Commission Project. It has started on March, 2013. It is designed as a lifetime companion for individual citizens that facilitates the collection of, and access to, long-term health-status information. A 4D avatar is a unique interface that allows data access, collection, sharing and analysis by utilizing modern ICT technology. It will become the citizen's lifelong companion, providing long-term and consistent health status information of the individual citizen along a timeline representing the citizen's life, starting from birth.

The 4D avatar functions as an interface to support the collection of, and access to, the complete medical information relating to individual citizen's health status, gathered from different sources, including medical data, documents, lifestyle and other personal information, represented along a timeline. In addition, it is an

<sup>&</sup>lt;sup>237</sup> Hachman M. <u>"Microsoft Launches 'HealthVault' Records-Storage Site"</u>. PCMAG.com. (Last accessed: 30/07/2014)

<sup>&</sup>lt;sup>238</sup> http://msdn.microsoft.com/en-us/healthvault/jj128027.aspx. (Last accessed: 30/07/2014)

<sup>&</sup>lt;sup>239</sup> <u>http://en.wikipedia.org/wiki/Microsoft\_HealthVault#cite\_note-1</u>. (Last accessed: 30/07/2014)



interface to access integrated predictive computer simulation models, which foresee the growth of the disease and the effect of treatment. The system has:

- Internal data repositories to store individual data for the avatars
- An internal model repository to store models commonly used by all the avatars.
- Links to external sources, such as hospitals' Electronic Health Records (EHRs) and other data and model repositories.

MyHealthAvatar is a tool that allows highly self-motivated data management and user-centred data collection, supported by the necessary data integrity measures.

Overall, it contributes to individualized disease prediction and prevention and supports healthy lifestyles and independent living<sup>240</sup>.

Despite the opportunities and benefits, major barriers hamper the wider uptake of PHR:

- lack of awareness of, and confidence in overall eHealth solutions among patients, citizens
- and healthcare professionals;
- lack of interoperability;
- limited large-scale evidence of the cost-effectiveness;
- lack of legal clarity for health and wellbeing mobile applications and the lack of transparency regarding the utilization of data collected by such applications;
- inadequate or fragmented legal frameworks including the lack of reimbursement schemes;
- high start-up costs involved in setting up various eHealth systems;
- regional differences in accessing ICT services, limited access in deprived areas.

# 3.6. Ethical and privacy issues

Here we discuss some of the legal, privacy, and ethical issues that rise with the development of personal health records and applications. While personal health applications have potential to improve patient health, they also may call for additional measures of patient privacy, and security. Some of these issues include:

- Obtaining adequate privacy consent from patients;
- Ensuring that the systems can accurately implement the consent options of patients, such as limiting access or prohibiting access to the PHR;
- Ensuring that only relevant information is collected;
- Privacy issues if the system involves a number of system vendors and subcontractors or cloud computing;
- Uniformity of the usage of medical terms and abbreviations;
- Clear understanding of the information flows and potential for leakage of personal health information to unapproved persons or overseas;
- Data security issues;
- Patient verification issues

For eHealth solutions to be trusted and accepted by patients and health professionals it is essential to ensure that the system is secure and the data are fully protected. Patients should be in charge of their own medical file, they should be able to 'log in' and inspect it. The option to access one's own information is a fundamental right that is embodied in the EU Data Protection legislation.

<sup>&</sup>lt;sup>240</sup> <u>http://www.myhealthavatar.eu/</u> (Last accessed: 30/07/2014)



Ensuring privacy and security of electronic health information is a key component to building the trust required to realize the potential benefits of electronic health information exchange<sup>241</sup>. If individuals and other participants in a network lack trust in electronic exchange of information due to perceived or actual risks to individually identifiable health information or the accuracy and completeness of such information, it may affect their willingness to disclose necessary health information and could have life-threatening consequences<sup>242</sup>.

First of all, informed consent should be the basis of all actions with regards to patient's medical data, whether it is exchange, analysis, adaptation or deletion of medical data. Patients have the right to know what data is collected and stored, how this data is accessed and processed and by whom, for how long data is retained and for what purpose, as well as what their rights are in case of breaches. Only when they are fully informed, they can make an accurate decision and provide their clear, free and explicit consent about the processing of their health data. In 2010 the Belgian Consumer Organization Test-Achats 21 asked consumers about their expectations of eHealth solutions: 95% of consumers expressed the desire to view their own medical files and 89% believe it is important to see who accessed their medical file.<sup>243</sup>

In order to be valid consent must be freely given, unambiguous, specific, explicit and informed. Exceptions should be considered in case of emergency care. Despite it is possible that such a consent may not be required when health data are processed by a health professional for reasons related to preventive medicines, medical diagnosis, the provision of case or treatment or the management of health-care services, the fact that the data included in the EHRs may be accessible to a variety of entities renders it important to clarify the application of the rules on consent and ensure the security of the data.

# 4. Sources of personalized information on lifestyle

# 4.1. Data source selection criteria

Sources of information for patients on the internet are exponentially increasing, varied and largely unregulated. The following criteria for on-line social media were considered:

- 1) popularity
- 2) relevance to posting personal information related to lifestyle and/or health issues.
- 3) availability of API: only sources with an API are included.

As of February 2014, 40 percent of the European population were accessing social media on any device. Furthermore, 26 percent of the region's population were mobile social media users<sup>244</sup>. Also, according to a recent (Feb 2014) report by the company WeAreSocial<sup>245</sup>, Facebook dominates in Western Europe, with 37 countries around the region accounting for a total of 232.2 million active users – roughly 19% of the platform's total global user base.

Although an increasing number of patient oriented social media are available, only general purpose social media sites are considered, so as to be able to extract information on general lifestyle issues, not biased by potential topic limitations that might be imposed by specialized social media sites.

<sup>&</sup>lt;sup>241</sup> Guide to Privacy and Security. The Office of the National Coordinator for Health Information Technology. Available at: http://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide-chapter-4.pdf

<sup>&</sup>lt;sup>242</sup> Ibid.

<sup>&</sup>lt;sup>243</sup> Analysing eHealth systems. Available at: https://www.privacyinternational.org/reports/privacy-and-security-indeveloping-countries-and-emergency-situations/analysing-ehealth#footnote6\_c9c8ym7

<sup>&</sup>lt;sup>244</sup> Statista Inc., The statistics portal, <u>http://www.statista.com/statistics/295648/social-media-penetration-in-europe/</u>

<sup>&</sup>lt;sup>245</sup> http://wearesocial.net/blog/2014/02/social-digital-mobile-europe-2014/



# 4.2. Sources of personalized information on lifestyle in CARRE

For the description of the identified on-line social media sites the following template has been created:

Table 10. Template for the description of social media sites		
Name	The public name of social media site.	
URL	A reference to each social media site.	
Description	A description of social media site.	
Users	Number of people that are registered in and/or use the social media site.	
API	Link to the API and short description	

Table 11. Soc	Table 11. Social media: Facebook		
Name	Facebook		
URL	https://www.facebook.com/		
Description	Facebook is an online social networking service. After registering to use the site, users may create a personal profile, add other users as friends, exchange messages, post status updates and photos, and receive notifications when others update their profiles. Additionally, users may join common-interest user groups, organized by workplace, school or college, or other characteristics, and categorize their friends into lists such as "People From Work" or "Close Friends".		
Users	More than 1 billion active users.		
API	Yes (https://developers.facebook.com/docs/graph-api)		

Table 12. Soci	Table 12. Social media: Twitter		
Name	Twitter		
URL	https://Twitter.com/		
Description	Twitter is an online social networking and microblogging service that enables users to send and read short 140-character text messages, called "tweets". Registered users can read and post tweets, but unregistered users can only read them. Users access Twitter through the website interface, SMS, or mobile device app.		
Users	More than 40 million users.		
API	Yes ( <u>https://dev.Twitter.com/</u> )		

Table 13. Soc	Table 13. Social media: Google+		
Name	Google+		
URL	https://plus.google.com/		
Description	Google has described Google+ as a "social layer" that enhances many of its online properties, and that it is not simply a social networking website, but also an authorship tool that associates web-content directly with its owner/author. Google+ User profile is a public visible account of a user that is attached to many Google properties. It includes basic social networking elements like a profile photo, about section, background photo, previous work and school history, interests, places lived and an area to post status updates.		
Users	540 million active users.		
API	Yes (https://developers.google.com/apis-explorer/#p/)		



Table 14. Soci	Table 14. Social media: YouTube		
Name	YouTube		
URL	http://www.youtube.com/		
Description	YouTube is a video-sharing website. The site allows users to upload, view, and share videos. Most of the content on YouTube has been uploaded by individuals, but media corporations including CBS, the BBC, Vevo, Hulu, and other organizations offer some of their material via YouTube, as part of the YouTube partnership program. Unregistered users can watch videos, and registered users can upload an unlimited number of videos. Most videos enable users to leave comments.		
Users			
API	Yes (https://developers.google.com/youtube/v3/getting-started)		

# 5. Sources of Medical Evidence

As presented in CARRE Deliverable D.2.2, CARRE relies on accessing state-of-the-art evidence based medicine data. This chapter presents evidence-based medicine resources.

# 5.1. Evidence-Based Medicine Resources

Evidence based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values<sup>246</sup>. In other words, it is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients<sup>247</sup>. To broaden its application from individual patients to health care services in general, EBM is also known as evidence-informed healthcare or evidence-based health care. The clinical approach is known as evidence based practice<sup>248</sup>.

# 5.2. Data source selection criteria

In CARRE medical experts use Centre for Evidence-based Medicine at the University of Oxford (OCEBM) Levels of Evidence (see D.2.1 Section 2.4.3. Medical evidence, p.34) to ascertain the evidence quality of the source. OCEBM Levels of Evidence is a hierarchy of the *likely* best evidence and it is designed so that it can be used *as a* short-cut for clinicians, researchers, or patients to find the likely best evidence.

The OCEBM Levels is not pre-appraised sources of evidence as Clinical Evidence, NHS Clinical Knowledge Summaries, UpToDate which may be more comprehensive, but in such a way it doesn't risk reliance on expert authority<sup>249</sup>.

As in databases research is made semi-automatically, one of the requirements for the evidence based information in CARRE is to provide information within the frames of internal validity (that means that the

<sup>&</sup>lt;sup>246</sup> Sackett DL, Straus SE, Richardson WS, et al. Evidence-based medicine: how to practice and teach EBM. 2d ed. Edinburgh: Churchill Livingstone, 2000.

<sup>&</sup>lt;sup>247</sup> Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. BMJ. Evidence based medicine: what it is and what it isn't.1996 Jan 13; 312(7023):71-2.

<sup>&</sup>lt;sup>248</sup> <u>http://en.wikipedia.org/wiki/Evidence-based\_medicine</u> (Last accessed:08/07/2014)

<sup>&</sup>lt;sup>249</sup> <u>http://www.cebm.net/2011-oxford-cebm-levels-evidence-introductory-document/</u> (Last accessed: 30/07/2014)



results of clinical research correct for the patients in the study) and generalizability (that means that the results of the study apply for the target population in CARRE (Use Cases))<sup>250</sup>.

## 5.2.1. The pyramid of evidence

The traditional blocks of EBM are described and widely applied by Sackett DL, Straus SE, Richardson WS, et *al.* (see Figure 59).

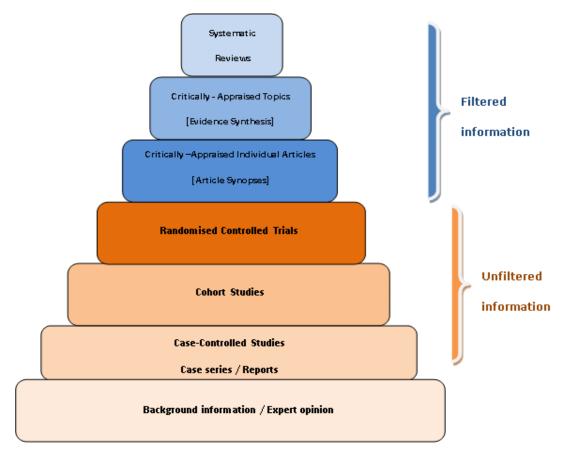


Figure 66. The pyramid of evidence

Based on this pyramid, databases make different search: some of them through filtered resources, which appraise the quality of studies and often make recommendations for practice. They include Systematic Reviews and Meta- Analysis; Evidence Syntheses and Article Synopses.

As evidence is not always available via filtered resources, it is possible to use specific search strategies in MEDLINE (e.g. PubMed) to achieve the highest possible level of evidence<sup>251</sup>. Although systematic reviews are also searchable in MEDLINE, e.g. PubMed using certain filters to achieve a result. In PubMed one can perform search data from the pyramid top to the bottom.

<sup>&</sup>lt;sup>250</sup> Fletcher R H. Evidence-basedmedicine. UpToDateInc. (Last accessed:08/07/2014)

<sup>&</sup>lt;sup>251</sup> <u>http://www.dartmouth.edu/~biomed/resources.htmld/guides/ebm\_resources.shtml</u>



# 5.3. Ethical and privacy issues

Davidoff and colleagues<sup>252</sup>identify five linked ideas as central to EBM. They write: 'Firstly, clinical decisions should be based on the best available scientific evidence; secondly, the clinical problem - rather than the habits of protocols - should determine the type of evidence to be sought; thirdly, identifying the best evidence means using epidemiological and biostatistical ways of thinking; fourthly, conclusions derived from identifying and critically appraising evidence are useful only if put into action in managing patients or making health care decisions; and, finally, performance should be constantly evaluated'.

Some ethical considerations of using "evidence" described in "evidence-based medicine" sources should be taken in mind. First of all, "evidence" is evidence for only a particular cohort under particular circumstances and may be entirely inapplicable in another. What is "evidence" for a 22-year-old male is not automatically applicable to a 66-year-old female. EBM speaks about a large statistical group of people and, therefore, cannot simply be mindlessly applied to the individual patient. EBM, unless it is tried in different groups and under different circumstances, must be used with great caution. We must know precisely what the criteria for selection were and why these were chosen and not others<sup>253</sup>.

Tony Hope in his article<sup>254</sup> very nicely describes an importance of evidence based medicine in the healthcare purchasing. He raises three ethical concerns:

- evidence based medicine may be used by those who are willing to cut funds of health care, as good evidence exist for rather small number of medical interventions and this allows to reduce health care expenditures,
- evidence based medicine could introduce a systematic bias into purchasing due to the fact that pharmaceutical companies are willingly funding drug research and not the research of other forms of treatment. This could result in some drug treatments being recommended, and purchased, not because they are better than alternative, non-drug treatments, but because the evidence for effectiveness is better. The bias may also rise as some research needs fewer resources and generates more evidence. For example, the desired outcome for an intervention aimed at correcting an acute medical problem is likely to be easier to measure than the less clear-cut, longer term outcomes of interventions for people with chronic disease.
- Health care purchasers may rely on evidence based medicine too much; therefore, some methods of treatment may be unavailable for an individual, because they are considered to be not a "best buy".

Evidence based medicine is not only of interest to purchasers, but also of value in improving clinical practice<sup>255</sup>. The practice of EBM is often based on particular medical guidelines (protocols), which are developed taking in mind available state-of-the-art evidence. However, this may also raise the ethical consideration as new evidence is generated rapidly and medical protocols should be wisely and timely updated to keep them up to date.

EBM protocols often switch physicians' attitude from "thinking" to "doing". EBM, for all its advantages in caring for the "usual case of "X," tends to suppress our curiosity and imagination<sup>256</sup>or at least tends to channel our curiosity and shape our imagination within narrow limits and, therefore, gets in the way of the sort of speculation<sup>257</sup>. They also somewhat limit what physicians can do in terms of laboratory tests, instrumental examinations, medication prescription, etc. When some deviation from a standard EBM protocol is allowed it stipulates further research and education.

EBM proponents and opponents have presumed a strong belief in the rational power of science: if only the best evidence would be pulled together, good clinicians would automatically follow those recommendations.

<sup>&</sup>lt;sup>252</sup> Davidoff F, Haynes B, Sackett D, Smith R. Evidence based medicine: a new journal to help doctors identify the information they need. British medical journal 1995; 310: 1085-1086

<sup>&</sup>lt;sup>253</sup> Loewy EH, Ethics and Evidence-Based Medicine: Is There a Conflict?, <u>http://www.medscape.com/viewarticle/559977 2</u>. (Last accessed: 11/07/2014)

<sup>&</sup>lt;sup>254</sup> Hope T, Evidence based medicine and ethics. Journal of medical ethics 1995; 21: 259-260.

<sup>255</sup> Ibid

<sup>&</sup>lt;sup>256</sup> Fitzgerald F. On being a doctor: curiosity. Ann Intern Med. 1999;130:70-72.

<sup>&</sup>lt;sup>257</sup> Loewy EH. Curiosity, imagination, compassion, science and ethics: do curiosity and imagination serve a central function? Health Care Anal. 1998;6:286-294.



This assumption ignores a key characteristic of professionalism: autonomy and discretion in professional work. Being a professional implies a covenant based on trust that the expert will act in the patient's best interest and that after years of education and credentialing, practitioners can be relied upon to make individual decisions. Practice guidelines, even if they have the authoritative imprimatur of professional organizations, remain weak tools to change professional attitudes and behaviour.

Professionals treat guidelines more as options than as true standards, and professional organizations do not enforce adherence to guidelines or reward guideline-following behaviour. Compliance with guidelines depends upon the fit between the standards and the goals of and demands on the individual health care provider. The evidence suggests that many clinicians find such a fit wanting.

# 5.4. Accessing sources of medical evidence

Sources of medical evidence and other medical authoritative information in CARRE will be used from PubMed database.

## PubMed

The PubMed comprises over 24 million citations for biomedical literature from MEDLINE, life science journals, and online books. PubMed is a free resource that is developed and maintained by the National Center for Biotechnology Information (NCBI), at the U.S. National Library of Medicine (NLM), located at the National Institutes of Health (NIH)<sup>258</sup>. As mentioned above, various strategies for searching most relevant information can be applied in this site.

They have Entrez Programming Utilities (E-utilities), available at <u>http://www.ncbi.nlm.nih.gov/books/NBK25497/</u>. Eight API followed by basic usage guidelines and requirements are described there. The Entrez Programming Utilities (E-utilities) are a set of nine server-side programs that provide a stable interface into the Entrez query and database system at the National Center for Biotechnology Information (NCBI). The E-utilities use a fixed URL syntax that translates a standard set of input parameters into the values necessary for various NCBI software components to search for and retrieve the requested data<sup>259</sup>.

In addition, copyright issues are described there. If one uses the E-utilities within software, NCBI's Disclaimer and Copyright notice (www.ncbi.nlm.nih.gov/About/disclaimer.html) must be evident to users of their product. All persons reproducing, redistributing, or making commercial use of this information are expected to adhere to the terms and conditions asserted by the copyright holder. If one wishes to do a large data mining project on PubMed data, they can enter into a licensing agreement and lease the data for free from National Library of Medicine (NLM). For more information on this is provided http://www.nlm.nih.gov/databases/leased.html<sup>26</sup>

Developing CARRE services, we do not dispose of using other databases for the search of medical evidence and other medical authoritative information, e.g.:

### The Cochrane Database of Systematic Reviews (CDSR)

The *CDSR* includes all Cochrane Reviews (and protocols) prepared by Cochrane Review Groups in The Cochrane Collaboration. Each Cochrane Review is a peer-reviewed systematic review that has been prepared and supervised by a Cochrane Review Group (editorial team) in The Cochrane Collaboration according to the *Cochrane Handbook for Systematic Reviews of Interventions* or *Cochrane Handbook for* 

<sup>&</sup>lt;sup>258</sup> <u>http://www.ncbi.nlm.nih.gov/pubmed/</u> (Last accessed: 08/07/2014)

<sup>&</sup>lt;sup>259</sup> http://www.ncbi.nlm.nih.gov/books/NBK25497/

<sup>&</sup>lt;sup>260</sup> Ibid 140

<sup>&</sup>lt;sup>261</sup> Ibid 140



*Diagnostic Test Accuracy Review*<sup>262</sup>. However, so far not all clinical questions have been systematically reviewed.

# EBSCO

EBSCO Information Services provides a complete and optimized research solution comprised of research databases, e-books and e-journals—all combined with the most powerful discovery service and management resources to support the information and collection development needs of libraries and other institutions and to maximize the search experience for researchers and other end users. EBSCO offers more than 375 full-text and secondary research databases and over 550,000 e-books plus subscription management services for 360,000 e-journals, e-journal packages and print journals. EBSCO also provides point-of-care decision support tools for healthcare professionals and organizational learning resources for training and development professionals<sup>263</sup>.

# Embase

Embase is a biomedical database with over 28 million indexed records from thousands of peer-reviewed journals and conference proceedings — over 6 million of which cannot be found in MEDLINE. What's more, all of the content is fully indexed using the Elsevier Life Science thesaurus Emtree — a hierarchically structured, controlled vocabulary for medicine and related life sciences<sup>264</sup>.

## Epistemonikos

Epistemonikos is a collaborative, multilingual database of research evidence and knowledge translation products. It includes systematic reviews, overviews of reviews, primary studies included in systematic reviews and structured summaries of that evidence<sup>265</sup>.

### Scopus

Scopus is the large abstract and citation database of peer-reviewed literature – scientific journals, books and conference proceedings. Delivering a comprehensive overview of the world's research output in the fields of science, technology, medicine social sciences and arts and humanities, Scopus features smart tools to track, analyse and visualize research. Scopus offers more 53 million records, 21,915 titles, 5,000 publishers<sup>266</sup>.

### Turning Research Into Practice (TRIP)

The TRIP is a clinical search engine designed to allow users to quickly and easily find and use high-quality research evidence to support their practice and/or care<sup>267</sup>. It simultaneously searches evidence-based sources of systematic reviews, practice guidelines, and critically-appraised topics and articles. Clinical search engine also searches MEDLINE's Clinical Queries, medical image databases, e-textbooks, and patient information leaflets. This site classifies by Publisher and Publishers are classified based on their output (e.g. Cochrane are classified in systematic reviews, New England Journal of Medicine as key primary research, etc.).

<sup>&</sup>lt;sup>262</sup> <u>http://www.thecochranelibrary.com/view/0/AboutTheCochraneLibrary.html#CDSR</u> (Last accessed: 08/07/2014).

<sup>&</sup>lt;sup>263</sup> <u>http://www.ebscohost.com/</u> (Last accessed: 12/07/2014).

<sup>&</sup>lt;sup>264</sup> <u>http://www.elsevier.com/online-tools/embase</u> (Last accessed: 12/07/2014).

<sup>&</sup>lt;sup>265</sup> <u>http://www.epistemonikos.org/en/about\_us/</u> (Last accessed: 12/07/2014).

<sup>&</sup>lt;sup>266</sup> <u>http://www.elsevier.com/online-tools/scopus</u> (Last accessed: 12/07/2014).

<sup>&</sup>lt;sup>267</sup> http://www.tripdatabase.com/about (Last accessed: 08/07/2014).



# 6. Sources Related to Patient Educational Resources

In the field of health science the use of the term patient empowerment is understood as an enabling process or outcome by which patients are promoted to autonomous self-regulation, self-management and selfefficacy in order to achieve maximum health and wellness.

According to the European Network on Patient Empowerment (ENOPE)<sup>268</sup> an empowered activated patients are able to:

- Understand their health condition and its effect on their body.
- Feel able to participate in decision-making with their healthcare professionals.
- Feel able to make informed choices about treatment.
- Understand the need to make necessary changes to their lifestyle for managing their condition.
- Is able to challenge and ask questions of the healthcare professionals providing their care.
- Take responsibility for their health and actively seeks care only when necessary
- Actively seek out, evaluate and make use of information.

The basic dimensions of patient empowerment have been identified<sup>269</sup> as (a) participation, (b) control and (c) education of patients. Apart from these three dimensions, Gibson's model<sup>270</sup> of patient empowerment refers the attributes of health professionals (i.e., nurses, doctors) as one of three patient empowerment domains. Moreover, Feste and Anderson described the empowerment of patients "as an educational process designed to help patients develop their knowledge, skills, attitudes, and degree of self-awareness necessary to effectively assume responsibility for their health-related decisions<sup>271</sup>.

The following tables present major sources of patient educational material available currently online.

# 6.1. Data source selection criteria

Sources of information for patients on the internet are exponentially increasing, varied and largely unregulated. The European Commission Quality Criteria for Health Related Websites were applied for selection of the sources related to patient education and decision support. These six criteria are: transparency and honesty, authority, privacy and data protection, updating of information, accountability and accessibility.

The following criteria for on-line patient educational sources selection were also considered:

- 1) relevance to the field of CARRE: educational material covering aspects related to cardiorenal syndrome and comorbidities as well as related issues, e.g. lifestyle, and diet.
- 2) reliability of the provider and accreditation of the material: based on the status of the provider and any available accreditation, including HONcode certification<sup>272</sup>.
- 3) availability of API: only sources with an API are included;

<sup>&</sup>lt;sup>268</sup> ENOPE, Patient Empowerment, 2014. (Last accessed: 28/07/2014). Available at: <u>http://enope.eu/patient-empowerment.aspx</u>.

<sup>&</sup>lt;sup>269</sup> Ouschan Robyn M Mgt, Sweeney Jillian C., Johnson Lester W. Dimensions of Patient Empowerment, Health Marketing Quarterly. 2000;18:1-2, 99-114,

<sup>&</sup>lt;sup>270</sup> Gibson CH. A concept analysis of empowerment. J Adv Nur. 1991;16:354–61,

<sup>&</sup>lt;sup>271</sup> Feste C., Anderson, R. M. Empowerment: From Philosophy to Practice. Patient Education and Counseling.1995; 26, 139-144.

<sup>&</sup>lt;sup>272</sup> HON, the Health On the Net Foundation (<u>http://www.hon.ch/</u>) is a Geneva based Non-Governmental Organization, internationally known for its pioneering work in the field of health information ethics, notably for the establishment of its code of ethical conduct, the HONcode. This is a code of ethics that guides site managers in setting up a minimum set of mechanisms to provide quality, objective and transparent medical information tailored to the needs of the audience.Sites applying for certification and sites already certified undertake to respect the HONcode and the requirements for certification. Currently the HONcode is used by over 7,300 certified websites, more than 10 million pages, covering 102 countries.



- 4) technological standards supported by the source: including medical vocabularies and terminologies; and
- 5) price: whether free or fee-based access is supported.

Most of the selected websites are official sites of American Diabetes Association (ADA), International Diabetes Federation (IDF), the National Institute of Diabetes and Digestive and Kidney Disease (NIDDKD), the American Society of Nephrology, National Kidney Disease Education Program, the National Kidney Foundation, the Academy of Nutrition and Dietetics, American Heart Association (AHA), American College of Cardiology, National Heart, Lung and Blood Institute, U.S. National Library of Medicine, Heart Failure Association of European Society of Cardiology, American Stroke Association etc. All information in these portals is the intellectual property of the organizations. The information found in the websites is based on the recent researches and updated regularly.

Ethical, privacy issues, terms of use are described in each website individually. The material provided within the websites is intended for educational and informational purposes only and the information contained in sites is not a substitute for medical advice or treatment.

# 6.2. On-line patient educational sources

For the description of the identified on-line data sources for patient educational material the following template has been created:

Table 15. Tem	Table 15. Template for the description of educational data sources		
Name	The public name of educational source.		
URL	The URL of the educational source.		
Description	A short description of educational source.		
Standards	Medical vocabularies, terminologies etc. supported by the source		
Language	Languages in which the educational material is available.		
Updates	How often the database is updated		
Accreditation	Certification of the reliability of the source and/or discussion on the reliability of the source provider		
API	Link to the API and short description		
Accessibility	How is the content of the database accessible and whether it is free or not.		
Comments	Any other comments		

Table 16. Edu	Table 16. Educational data source: MedlinePlus			
Name	MedlinePlus			
URL	http://www.nlm.nih.gov/medlineplus/			
Description	MedlinePlus is the National Institutes of Health's Web site for patients and their caregivers. Produced by the National Library of Medicine, it includes information about diseases, conditions, and wellness issues in common language. MedlinePlus offers reliable, up-to-date health information about the latest treatments, drugs or supplements, meanings of words, or medical videos or illustrations. Also includes links to the latest medical research on each topic and information about clinical trials on a disease or condition.			
Standards	<ul> <li>For problem code requests, MedlinePlus Connect supports:</li> <li>ICD-9-CM (International Classification of Diseases, 9th edition, Clinical Modification)</li> <li>ICD-10-CM (International Classification of Diseases, 10th edition, Clinical Modification)</li> <li>SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms). Note:</li> </ul>			



	<ul> <li>MedlinePlus Connect coverage of SNOMED CT focuses on CORE Problem List Subset codes (Clinical Observations Recording and Encoding) and their descendants</li> <li>MedlinePlus Connect supports HL7 Context-Aware Knowledge Retrieval (Infobutton) standard.</li> <li>For medication requests, MedlinePlus Connect supports: <ul> <li>RXCUI (RxNorm Concept Unique Identifier)</li> <li>NDC (National Drug Code)</li> </ul> </li> <li>For lab test requests, MedlinePlus Connect supports: <ul> <li>LOINC (Logical Observation Identifiers Names and Codes)</li> </ul> </li> <li>MedlinePlus uses a custom consumer health vocabulary for its 850+ health topics. Associated vocabulary terms (including synonyms, see references, and MeSH headings) are available for each health topic via an XML file.</li> </ul>
Language	English and Spanish
Updates	Updated and reviewed continuously.
Accreditation	HONcode compliant
	https://www.healthonnet.org/HONcode/Conduct.html?HONConduct166259
API	<ul> <li>Yes, available at: <u>http://www.nlm.nih.gov/api/index.html</u></li> <li>MedlinePlus Health topics API (<u>http://www.nlm.nih.gov/medlineplus/webservices.html</u>): Provides access to MedlinePlus health topic data in XML format. The service accepts keyword searches as requests and returns links to relevant English-language health topics in ranked order. The output also includes supplemental data such as health topic summaries, related vocabulary, and keyword-in-context snippets.</li> <li>MedlinePlus XML files (<u>http://www.nlm.nih.gov/medlineplus/xml.html</u>): MedlinePlus publishes three types of health topic XML files daily (Tuesday-Saturday): <ul> <li>MedlinePlus Health Topic XML: records for all English and Spanish health topics;</li> <li>MedlinePlus Compressed Health Topic XML: the same information as above, but in a zipped format; and</li> <li>MedlinePlus Connect API (<u>http://www.nlm.nih.gov/medlineplus/connect/service.html</u>): This API lets electronic health record (EHR) systems use standard clinical vocabularies to bring users health information from MedlinePlus</li> </ul></li></ul>
Accessibility	Free of charge and does not require registration or licensing. Applications should indicate that the information is from MedlinePlus.gov. Any application that makes use of NLM data include the following statement: "This product uses publicly available data from the U.S. National Library of Medicine (NLM), National Institutes of Health, Department of Health and Human Services; NLM is not responsible for the product and does not endorse or recommend this or any other product."
Comments	MedlinePlus Health topics API: NLM requires that users of the MedlinePlus Web service send no more than 85 requests per minute per IP address. Requests that exceed this limit will not be serviced, and service will not be restored until the request rate falls beneath the limit. The MedlinePlus Web service is updated once per day, Tuesday-Saturday. To limit the number of requests that you send to the Web service, NLM recommends caching results for a 12-24 hour period

Table 17. Educational data source: healthfinder.gov	
Name	healthfinder.gov
URL	http://www.healthfinder.gov/



Description	Healthfinder.gov includes updated information about diseases, conditions, health news and wellness issues. Healthfinder.gov is part of U.S. Department of Health & Human Services (HHS.gov)
Standards	
Language	English and Spanish
Updates	content frequently updated every 2 weeks, typically around the 15th and last day of each month
Accreditation	HONcode (http://www.hon.ch/HONcode/Conduct.html?HONConduct898345)
API	Yes available at: <a href="http://www.healthfinder.gov/Developer/">http://www.healthfinder.gov/Developer/</a> Health Topics A to Z ( <a href="http://healthfinder.gov/HealthTopics/">http://healthfinder.gov/Healthfinder.gov/Second Second Secon</a>
Accessibility	No charge – registration/confirmation based – terms of use available at: http://healthfinder.gov/Developer /http://healthfinder.gov/Developer/Term_of_Use.aspx
Comments	support team available to answer technical questions and consider adding new functionalities in the API ( <u>http://healthfinder.gov/Developer/FAQ.aspx</u> )

Table 18. Edu	Table 18. Educational data source: ClinicalTrials.gov	
Name	ClinicalTrials.gov	
URL	http://clinicaltrials.gov/ct2/home	
Description	ClinicalTrials.gov provides patients, family members, and members of the public current information about clinical research studies. ClinicalTrials.gov contains summary information about clinical studies being conducted throughout the United States and in many countries throughout the world. These data are provided to the National Library of Medicine by organizations and institutions that sponsor and implement the studies.	
Standards	MeSH	
Language	English	
Updates	Daily	
Accreditation	HONcode (https://www.healthonnet.org/HONcode/Conduct.html?HONConduct533410)	
API	download database extracts at: <u>http://clinicaltrials.gov/ct2/info/linking</u> Search capability available at: <u>http://clinicaltrials.gov/ct2/resources/download#UseURL</u>	
Accessibility	No charge	
Comments		

Table 19. Educational data source: AllRefer.com Health	
Name	AllRefer.com Health
URL	http://health.allrefer.com/
Description	A medical and health information resource containing a database of health articles and reference materials for consumers and health professionals alike. has extensive information from trusted sources on over 4,000 topics including diseases, tests, symptoms, injuries,



	surgeries, nutrition, poisons, and special topics. There is also focus on family and community health.
	Content:
	<ul> <li>Medical Encyclopedia - Extensive information on over 4000 topics arranged in an A- Z order covering diseases, symptoms, tests, surgery, injuries, nutrition, medications, and poisons.</li> </ul>
	<ul> <li>Disease &amp; Conditions - Extensive information on more than 1600 diseases, conditions, illnesses, and disorders. Covers causes, symptoms, diagnosis, and treatment.</li> </ul>
	<ul> <li>Medical Symptoms - Covers over 300 specific symptoms, such as abdominal pain, headaches, or heart palpitations, to allow users to search topics by what they are experiencing.</li> </ul>
	<ul> <li>Injuries &amp; Wounds - Profiles more than 60 common injuries from animal bites to whiplash. Educates about causes, signs of an emergency, symptoms, first aid, prevention, and treatment.</li> </ul>
	<ul> <li>Diet &amp; Nutrition - Explore topics ranging from vitamins and minerals, to additives in food, school lunches, vegetarianism, and more. Provides overview, dosage recommendations, side effects and food sources.</li> </ul>
	<ul> <li>Medical Tests &amp; Exams - Over 600 topics that cover everything from an abdominal computerized tomography scan to X-rays. Includes indications, preparation, risks, expectations, normal and abnormal values, and result evaluation.</li> </ul>
	<ul> <li>Surgery &amp; Procedures - Provides detailed patient guides on 100 common surgeries from gastrointestinal conditions to plastic surgery. Includes indications, risks, and expectations after surgery, and recovery.</li> </ul>
	<ul> <li>Special Topics - Explore more than 500 topics ranging from exercise, to smoking cessation, to travel tips.</li> </ul>
	<ul> <li>Poisons &amp; Overdoses - Information on over 300 poisoning and overdosing topics, ranging from acetaminophen, to brown recluse spider, to window cleaners.</li> </ul>
	<ul> <li>Health News - Find the latest news and research in the field of medicine and health.</li> </ul>
Standards	
Language	English
Updates	regularly, daily news
Accreditation	HONcode (https://www.hon.ch/HONcode/Conduct.html?HONConduct269452)
API	allows linking, search box (no framing)
	http://health.allrefer.com/about/link-to-us.html
Accessibility	No charge
Comments	

Table 20. Educational data source: Wikipedia: WikiProject Medicine	
Name	Wikipedia: WikiProject Medicine
URL	http://en.wikipedia.org/wiki/Wikipedia:WikiProject_Medicine
Description	Part of Wikipedia pages referring to medical topics which is reviewed regularly by a board of medical experts
Standards	ICD9/10, MeSH
Language	English, and multilingual 29,072 pages in English more than 1000 pages in 35 languages



	at least 1 page in 255 languages
Updates	expert crowd editing. partnership with Cochrane
Accreditation	assert
API	http://www.mediawiki.org/wiki/API
Accessibility	no charge
Comments	

Table 21. Educational data source: Wikiversity	
Name	Wikiversity
URL	https://en.wikiversity.org/wiki/Wikiversity:Main_Page
Description	A Wikimedia foundation project devoted to learning resources and learning projects
Standards	
Language	
Updates	expert crowd editing. partnership with Cochrane
Accreditation	
API	http://www.mediawiki.org/wiki/API
Accessibility	no charge
Comments	

Table 22. Educational data source: Kidney patients guide	
Name	Kidney patients guide
URL	http://www.kidneypatientguide.org.uk/contents.php
Description	Information on what patients say, physical aspects, treatment, emotional effects, diet, financial implications, holidays, carers, family and friends, support groups. The site is the result of collaboration between health care professionals, experts in information technology and multimedia, specialist health care writers, and - above all - people with renal failure, their families and carers. Also, they have kidney patients forum
Standards	Own glossary, based on medical terms, ICD9/10
Language	English
Updates	Updated not regularly
Accreditation	HONcode standard for trustworthy health
API	Patients forum
Accessibility	Free of charge
Comments	Articles were written by Dr Peter Rutherford, a healthcare professional at University of Wales College of Medicine, and Al Brookes, a freelance patient information consultant

Table 23. Educational data source: ASN online	
Name	Kidney patients guide
URL	https://www.asn-online.org/kidneydisease/
Description	Information for patients, care providers and medical professionals on kidney disease, ESKD,



	transplant, acute kidney injury, kidney stones, chronic kidney disease.
Standards	ICD9/10
Language	English
Updates	Continuously
Accreditation	HONcode standard for trustworthy health
API	Following RSS, Facebook, Twitter, YouTube, Flickr, LinkedIn, podcasts, blog
Accessibility	Free of charge
Comments	The American Society of Nephrology (ASN) leads the fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients

Table 24. Edu	Table 24. Educational data source: National Kidney Disease Education Program	
Name	National Kidney Disease Education Program	
URL	http://nkdep.nih.gov/index.shtml	
Description	Information on kidney disease, living with kidney disease, identifying and management, laboratory evaluation, federal response to CKD, resource center	
Standards	ICD9/10	
Language	English, Spanish	
Updates	Continuously	
Accreditation	HONcode standard for trustworthy health	
API	Following Facebook, Twitter, YouTube	
Accessibility	Free of charge	
Comments	The National Kidney Disease Education Program (NKDEP) is a sponsored effort of National Institute of Diabetes and Digestive and Kidney/ National Institutes of Health that works to reduce the burden of chronic kidney disease, especially among communities most impacted by the disease. NKDEP works in collaboration with a range of government, non-profit, and health care organizations to raise awareness, improve the understanding, detection, and management of kidney disease	

Table 25. Edu	Table 25. Educational data source: The National Kidney Foundation	
Name	The National Kidney Foundation	
URL	http://www.kidney.org/patients/	
Description	Information on Prevention kidney disease, how kidneys work, dialysis, patients and family resources, emergency resources, organ donation and transplantation, events, advocacy. Also, quiz, rate your risk quiz, food coach available	
Standards	ICD9/10	
Language	English, Spanish	
Updates	Continuously	
Accreditation	HONcode standard for trustworthy health	
API	Following Facebook, Twitter, Google+, LinkedIn, Instagram	
Accessibility	Free of charge	



Comments	The National Kidney Foundation is the leading organization in the U.S. dedicated to the
	awareness, prevention and treatment of kidney disease for hundreds of thousands of
	healthcare professionals, millions of patients and their families, and tens of millions of
	Americans at risk

Table 26. Edu	Table 26. Educational data source: Baxter Healthcare Ltd	
Name	Renal info	
URL	http://www.renalinfo.com/us/	
Description	Information on what is kidney disease, treatment: early stage, end stage, dialysis center, lifestyle: coping and living with kidney disease, support.	
Standards	ICD9/10	
Language	Multilingual	
Updates	Continuously reviewed and updated	
Accreditation	HONcode standard for trustworthy health	
API	Following YouTube, Twitter	
Accessibility	Free of charge	
Comments	A web site designed and developed to provide information and support to those affected by kidney failure. It is supported through and educational grant from Baxter Healthcare Ltd, a company that supplies dialysis equipment and services to kidney patients worldwide. The information provided on the site has been written and edited by the medical experts	

Table 27. Edu	Table 27. Educational data source: Kidney patients guide	
Name	Kidney patients guide	
URL	http://www.kidneypatientguide.org.uk/contents.php	
Description	Information on what patients say, physical aspects, treatment, emotional effects, diet, financial implications, holidays, carers, family and friends, support groups. The site is the result of collaboration between health care professionals, experts in information technology and multimedia, specialist health care writers, and - above all - people with renal failure, their families and carers. Also, they have kidney patients forum	
Standards	Own glossary, based on medical terms, ICD9/10	
Language	English	
Updates	Updated not regularly	
Accreditation	HONcode standard for trustworthy health	
API	Patients forum	
Accessibility	Free of charge	
Comments	Articles were written by Dr Peter Rutherford, a healthcare professional at University of Wales College of Medicine, and Al Brookes, a freelance patient information consultant	

Table 28. Educational data source: ASN online	
Name	Kidney patients guide
URL	https://www.asn-online.org/kidneydisease/
Description	Information for patients, care providers and medical professionals on kidney disease, ESKD, transplant, acute kidney injury, kidney stones, chronic kidney disease.



Standards	ICD9/10
Language	English
Updates	Continuously
Accreditation	HONcode standard for trustworthy health
API	Following RSS, Facebook, Twitter, YouTube, Flickr, LinkedIn, podcasts, blog
Accessibility	Free of charge
Comments	The (ASN) leads the fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients

Table 29. Edu	cational data source: National Kidney Disease Education Program
Name	National Kidney Disease Education Program
URL	http://nkdep.nih.gov/index.shtml
Description	Information on kidney disease, living with kidney disease, identifying and management, laboratory evaluation, federal response to chronic kidney disease, resource center
Standards	ICD9/10
Language	English, Spanish
Updates	Continuously
Accreditation	HONcode standard for trustworthy health
API	Following Facebook, Twitter, YouTube
Accessibility	Free of charge
Comments	The National Kidney Disease Education Program (NKDEP) is a sponsored effort of National Institute of Diabetes and Digestive and Kidney/ National Institutes of Health that works to reduce the burden of chronic kidney disease, especially among communities most impacted by the disease. NKDEP works in collaboration with a range of government, non-profit, and health care organizations to raise awareness, improve the understanding, detection, and management of kidney disease

Table 30. Edu	Table 30. Educational data source: The National Kidney Foundation	
Name	The National Kidney Foundation	
URL	http://www.kidney.org/patients/	
Description	Information on Prevention kidney disease, how kidneys work, dialysis, patients and family resources, emergency resources, organ donation and transplantation, events, advocacy. Also, quiz, rate your risk quiz, food coach available	
Standards	ICD9/10	
Language	English, Spanish	
Updates	Continuously	
Accreditation	HONcode standard for trustworthy health	
API	Following Facebook, Twitter, Google+, LinkedIn, Instagram	
Accessibility	Free of charge	
Comments	The National Kidney Foundation is the leading organization in the U.S. dedicated to the awareness, prevention and treatment of kidney disease for hundreds of thousands of healthcare professionals, millions of patients and their families, and tens of millions of Americans at risk	



Table 31. Edu	Table 31. Educational data source: Baxter Healthcare Ltd	
Name	Renal info	
URL	http://www.renalinfo.com/us/	
Description	Information on what is kidney disease, treatment: early stage, end stage, dialysis center, lifestyle: coping and living with kidney disease, support.	
Standards	ICD9/10	
Language	Multilingual	
Updates	Continuously reviewed and updated	
Accreditation	HONcode standard for trustworthy health	
API	Following YouTube, Twitter	
Accessibility	Free of charge	
Comments	A web site designed and developed to provide information and support to those affected by kidney failure. It is supported through and educational grant from Baxter Healthcare Ltd, a company that supplies dialysis equipment and services to kidney patients worldwide. The information provided on the site has been written and edited by the medical experts	

Table 32. Edu	able 32. Educational data source: Heart.org (American Heart Association)	
Name	Heart.org	
URL	http://www.heart.org/HEARTORG/GettingHealthy/GettingHealthy_UCM_001078_SubHomeP age.jsp	
Description	The website of AHA. The American Heart Association (AHA) is the nation's oldest, largest voluntary organization devoted to fighting cardiovascular diseases and stroke. The American Heart Association is working to help kids, families and communities live heart-healthy lives. The website provides health education in a variety of ways (healthy life, diseases and conditions, healthcare and research, information for caregivers, educators).	
Standards	ICD9/10	
Language	English, Spanish, Traditional Chinese, Simplified Chinese, Vietnamese	
Updates	Irregular	
Accreditation	HONcode compliant	
	https://www.healthonnet.org/HONcode/Conduct.html?HONConduct517595	
	Compliance with the National Health Council Standards of Excellence Certification Program®	
ΑΡΙ	Allows linking: <u>http://www.heart.org/HEARTORG/General/American-Heart-Association-and-American-Stroke-Association-Linking-Policy_UCM_303551_Article.jsp</u> Definitions A to Z: <u>http://www.heart.org/HEARTORG/Conditions/The-Heart-and-Stroke-Encyclopedia_UCM_445688_SubHomePage.jsp</u> . Allows to get a brief definition of dozens of cardiovascular terms from our Heart and Stroke Encyclopedia and get links to in-depth information. Following Facebook, Twitter, YouTube, Google+, LinkedIn, Instagram, Pinterest, RSS	
Accessibility	Free of charge	
Comments	-	



Table 33. Edu	Table 33. Educational data source: Hearthub.org (American Heart Association)	
Name	Hearthub.org (linking to Heart.org)	
URL	http://www.hearthub.org/ (linking to www.heart.org)	
Description	HeartHub is the American Heart Association's patient portal for information, tools and resources about cardiovascular disease and stroke. The website provides information to help the patients understand and manages their health, understand their risk and treatment options.	
Standards	ICD9/10	
Language	English	
Updates	Irregular	
Accreditation	HONcode compliant <u>https://www.healthonnet.org/HONcode/Conduct.html?HONConduct517595</u> Compliance with the National Health Council Standards of Excellence Certification Program®	
API	Allows linking: <u>http://www.heart.org/HEARTORG/General/American-Heart-Association-and-American-Stroke-Association-Linking-Policy_UCM_303551_Article.jsp</u> Following Twitter	
Accessibility	Free of charge	
Comments	The website is linking to www.heart.org	

Table 34. Educational data source: CardioSmart (American College of Cardiology)	
Name	CardioSmart
URL	https://www.cardiosmart.org/
Description	The website of the American College of Cardiology. The website is for the patient education and empowerment. The mission is to help individuals prevent, treat and manage cardiovascular disease. Provides information about heart conditions and basics, drugs and treatment, healthy living and other.
Standards	ICD9/10
Language	English, Spanish
Updates	Irregular
Accreditation	The American College of Cardiology. <i>CardioSmart</i> is overseen by the Patient-Centered Care Committee of the College.
API	Allows linking: <u>https://www.cardiosmart.org/About</u> Health Topics A to Z ( <u>https://www.cardiosmart.org/AZ-Topics</u> ). This API provides easy-to- understand descriptions of the most common heart disease conditions, including heart attack, congestive heart failure, and hypertension (high blood pressure), among others. Glossary ( <u>https://www.cardiosmart.org/Glossary</u> ). This API helps find definitions for thousands of medical terms, treatments, and tests even health-related abbreviations, prefixes, and suffixes. Following Facebook, Twitter, YouTube, RSS, mobile apps, newsletters
Accessibility	Free of charge. In order to access certain content and to make use of the advanced personalization features of the Site, it is required to register and obtain a personal User Name and Password. Terms of use available at: <u>https://www.cardiosmart.org/About/Terms-and-Conditions</u>



Comments	The mission of the American College of Cardiology (ACC) is to transform cardiovascular care	
	and improve heart health. ACC represents the majority of board-certified U.S. cardiovascular	
	physicians.	

Table 35. Educational data source: Heartfailurematters.org	
Name	Heartfailurematters.org
URL	http://www.heartfailurematters.org/en_GB
Description	The website is developed under the direction of the <u>Heart Failure Association of the</u> <u>European Society of Cardiology</u> (HFA of the ESC). The information presented in the website is based on recommendations in accordance with European Practice Guidelines. Provides the information about heart failure, what can the doctor do, what can the patient do, living with heart failure, warning signs, animated journey through heart failure.
Standards	ICD9/10
Language	English, German, Dutch, Spanish, French, Russian, Greek, Arabic
Updates	Continuously
Accreditation	HONcode compliant
	https://www.healthonnet.org/HONcode/Conduct.html?HONConduct363183
	The content of the website is based on recommendations in accordance with European Practice Guidelines.
API	Following Facebook
Accessibility	Free of charge
Comments	The HFA of the ESC's mission is to improve quality of life and longevity, through better prevention, diagnosis and treatment of heart failure, including the establishment of networks for its management, education and research.

Table 36. Educational data source: Strokeassociation.org (American Heart Association, American Stroke Association)	
Name	Strokeassociation.org (American Heart Association, American Stroke Association)
URL	http://www.strokeassociation.org/STROKEORG/
Description	The website of the American Stroke Association (ASA). Created in 1997, ASA is dedicated to prevention, diagnosis and treatment to save lives from stroke. On website the patient can find information about the stroke (types, risk factors, diagnosis, treatment), warning signs, life after stroke.
Standards	ICD9/10
Language	English, Spanish, Traditional Chinese, Simplified Chinese, Vietnamese
Updates	Irregular
Accreditation	Compliance with the National Health Council Standards of Excellence Certification Program®
API	Following Facebook, Twitter, YouTube
Accessibility	Free of charge
Comments	-

Table 37. Educational data source: National Heart, Lung and Blood Institute		
Name	National Heart, Lung and Blood Institute	(U.S. Department of Health & Human Services,



	National Institutes of Health)
URL	http://www.nhlbi.nih.gov/health/index.htm
Description	The website of the National Heart, Lung, and Blood Institute (NHLBI). NHLBI provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases. Provides health information for the publics about heart and vascular disease, health assessment tools.
Standards	ICD9/10
Language	English, Spanish
Updates	Irregular
Accreditation	U.S. Department of Health & Human Services, National Institutes of Health
API	Health Topics A to Z ( <u>http://www.nhlbi.nih.gov/health/health-topics/by-alpha/#section_A</u> ). Provides science-based, plain-language information related to heart, lung, and blood diseases and conditions and sleep disorders. The site contains articles on diseases, conditions, tests, procedures, and other relevant topics, which can be e-mailed, printed, and shared. Search ( <u>http://www.nhlbi.nih.gov/cgi-bin/search/</u> ). Linking to Google Search. Following Facebook, Twitter, YouTube, Google
Accessibility	Free of charge. The Web pages of the National Heart, Lung, and Blood Institute have been designed to make them accessible to all users and compatible with screen readers and other assistive technologies. However, it is possible that you may encounter problems when accessing certain pages. A link has been added at the very bottom of every page that goes to this page.
Comments	-

Table 38. Educational data source: UpToDate	
Name	UpToDate
URL	http://www.uptodate.com/contents/coronary-heart-disease-the-basics
Description	Wolters Kluwer Health is a leading global provider of information for the healthcare industry. One of the major brands is UpToDate. UpToDate is an evidence-based, physician-authored clinical decision support resource which clinicians trust to make the right point-of-care decisions. All topics are updated as new evidence becomes available. Provides the patient information topics on diseases, conditions, diagnosis and treatment.
Standards	ICD9/10
Language	English, German, Spanish, French, Italian, Portuguese
Updates	Continuously updated to incorporate new medical findings
Accreditation	-
API	-
Accessibility	Patient information is free of charge
Comments	-

Table 39. Educational data source: Mayo Clinic	
Name	Mayo Clinic
URL	http://www.mayoclinic.org/patient-care-and-health-information



Description	Mayo Clinic is non-profit worldwide leader in medical care, research and education for people from all walks of life. The website provides information about diseases and conditions (definition, symptoms, causes, risk factors, complications, tests, diagnosis, treatment, drugs, lifestyle, prevention), healthy lifestyle and other.
Standards	ICD9/10
Language	English, Spanish, Portuguese, Arabic, Mandarin
Updates	Irregular
Accreditation	HONcode compliant https://www.hon.ch/HONcode/Conduct.html?HONConduct636199
API	Following Facebook, Twitter, YouTube, Google, Pinterest
Accessibility	Free of charge
Comments	More than 3,300 physicians, scientists and researchers from Mayo Clinic share their expertise to empower the patient.

Table 40. Edu	Table 40. Educational data source: WebMD	
Name	WebMD	
URL	http://www.webmd.com/a-to-z-guides/common-topics/default.htm	
Description	WebMD provides valuable health information, tools for managing your health, and support to those who seek information. The patient can find the information about diseases and conditions (symptoms, diagnosis, treatment, living, managing, support)	
Standards	ICD9/10	
Language	English	
Updates	Irregular	
Accreditation	HONcode compliant http://www.hon.ch/HONcode/Conduct.html?HONConduct298987 URAC's Health Web Site Accreditation (https://www.urac.org/directory/CompanyView.aspx?cid=C8700000F48)	
API	Following Facebook, Twitter, Pinterest	
Accessibility	Free of charge. If the user chooses to register or update an existing member profile with WebMD or access certain functionality on the WebMD Web Sites, she/he may be required to submit Personal Information. The website user is responsible for taking all reasonable steps to ensure that no unauthorized person shall have access to his WebMD passwords or accounts.	
Comments	WebMD is the organization that provides credible information, supportive communities, and in-depth reference material about health subjects on the Internet. WebMD verifies the qualifications of their medical professionals on the site. Health Professionals, including those who write, review and edit our editorial content as well as Community Experts, undergo credential verification by a third party.	

Table 41. Educational data source: MedicineNet.com	
Name	MedecineNet.com
URL	http://www.medicinenet.com/diseases_and_conditions/article.htm
Description	MedicineNet is an online, healthcare media publishing company. Founded in 1996, MedicineNet.com has had a highly accomplished, uniquely experienced team of qualified



	executives in the fields of medicine, healthcare, Internet technology, and business to bring you the most comprehensive, sought-after healthcare information anywhere. Provides information about diseases and conditions, medications, heath and living, MedTerm dictionary, symptom checker, image collection
Standards	ICD9/10
Language	English
Updates	Irregular
Accreditation	HONcode compliant
	https://www.hon.ch/HONcode/Conduct.html?HONConduct594277
API	Following Facebook, Twitter, newsletter, RSS
Accessibility	Free of charge
Comments	WebMD acquired MedicineNet in 2004.

Table 42. Edu	cational data source: Diabetes.org (American Diabetes Association (ADA)					
Name	Diabetes.org (American Diabetes Association (ADA)					
URL	http://www.diabetes.org/					
Description	Official site of American Diabetes Association (ADA). Provides information about prevention, diagnosis, basics, types of diabetes, living with diabetes, nutrition, fitness and other practical information.					
Standards	ICD9/10					
Language	English, Spanish					
Updates	Irregular					
Accreditation	Compliance with the National Health Council Standards of Excellence Certification Program®					
API	Following Facebook, Twitter, YouTube, Instagram, Pinterest					
Accessibility	Free of charge					
Comments	The mission of ADA is to prevent and cure diabetes, to improve the lives of all people affected by diabetes and to fight against the deadly consequences of diabetes.					

Table 43. Educational data source: International Diabetes Federation (IDF)						
Name	International Diabetes Federation (IDF)					
URL	http://www.idf.org/about-diabetes					
Description	The website of the International Diabetes Federation (IDF). Provides information about diabetes prevention, risk factors, signs and symptoms, complications, facts and figures, education programmes and other.					
Standards	ICD9/10					
Language	English					
Updates	Irregular					
Accreditation	-					
API	Following Facebook, Twitter, YouTube, LinkedIn, Flickr, newsletters					
Accessibility	Free of charge					
Comments	The mission of the International Diabetes Federation is to promote diabetes care, prevention					



and a cure worldwide. The activities of IDF aim to influence policy, increase public
awareness and encourage health improvement, promote the exchange of high-quality
information about diabetes, and provide education for people with diabetes and their
healthcare providers. IDF's awareness and advocacy initiatives are grounded in the
experiences of our global network of national diabetes associations.

Table 44. Educational data source: National Diabetes Information Clearinghouse (NDIC)							
Name	National Diabetes Information Clearinghouse (NDIC) ( <u>U.S. Department of Health &amp; Human</u> <u>Services</u> , <u>National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</u> , <u>National Institutes of Health (NIH)</u> )						
URL	http://diabetes.niddk.nih.gov/dm/ap.aspx						
Description	An information of the National Institute of Diabetes and Digestive and Kidney Disease (NIDDKD), <u>National Institutes of Health (NIH)</u> . Provides information about diabetes to people with diabetes and to their families, health care professionals, and the public.						
Standards	ICD9/10						
Language	English, Spanish						
Updates	Irregular						
Accreditation	HONcode compliant						
	https://www.healthonnet.org/HONcode/Conduct.html?HONConduct166422						
API	List of Topics and Titles A to Z ( <u>http://diabetes.niddk.nih.gov/dm/a-z.aspx</u> ).						
	Facilitates the information search on diabetes.						
	Following Facebook, Twitter, Google, Gmail, blog, Yahoo mail, Amazon and more others						
Accessibility	Free of charge						
Comments	The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.						

Table 45. Edu	Table 45. Educational data source: Joslin Diabetes Center					
Name	Joslin Diabetes Center					
URL	http://www.joslin.org/newly-diagnosed.html					
Description	The website provides patient's information about diabetes and nutrition, diabetes and exercise, childhood diabetes, newly diagnosed diabetes, online diabetes classes and other.					
Standards	ICD9/10					
Language	English, Spanish (some information)					
Updates	Irregular					
Accreditation	-					
API	Following RSS, Facebook, Twitter, YouTube, blog, LinkedIn					
Accessibility	Free of charge					
Comments	Joslin Diabetes Center, located in Boston, Massachusetts, is the world's largest diabetes research and clinical care organization. Joslin is dedicated to ensuring that people with diabetes live long, healthy lives and offers real hope and progress toward diabetes prevention and a cure. Joslin is an independent, non-profit institution affiliated with Harvard					



Medical School.

Table 46, Edu	cational data source: Weight Control Information Network (WIN)					
Name	Weight Control Information Network (WIN)					
URL	http://win.niddk.nih.gov/publications/index.htm#public					
Description	An information service of the National Institute of Diabetes and Digestive and Kidney Disease (NIDDKD). Weight Control Information Network provides the general public, health professionals, and the media with up-to-date, science-based information on obesity, weight control, physical activity, and related nutritional issues.					
Standards	ICD9/10					
Language	English, Spanish (some information)					
Updates	Irregular					
Accreditation	HONcode compliant					
	https://www.healthonnet.org/HONcode/Conduct.html?HONConduct055296					
API	Following Facebook					
Accessibility	Free of charge					
Comments	The Weight-control Information Network (WIN) is an information service of the <u>National</u> <u>Institute of Diabetes and Digestive and Kidney Diseases</u> (NIDDK), part of the <u>National</u> <u>Institutes of Health</u> (NIH).					

Table 47. Educational data source: Eatright.org (The Academy of Nutrition and Dietetics)							
Name	Eatright.org (The Academy of Nutrition and Dietetics)						
URL	http://www.eatright.org/Public/						
Description	The Academy of Nutrition and Dietetics Foundation is the world's largest charitable organization devoted exclusively to nutrition and dietetics. The Academy of Nutrition and Dietetics strives to improve the nation's health and advance the profession of dietetics through research, education, and advocacy. The mission is to empower members to be food and nutrition leaders. The Academy and its members are committed to optimizing the nation's health by providing scientifically sound nutrition information to the public. The website provides public information about food and nutrition, children's, women's, men's health, healthy weight, diseases and health conditions, sports, exercise and other.						
Standards	ICD9/10						
Language	English, Spanish, Chinese (some information)						
Updates	Irregular						
Accreditation	-						
API	Following Facebook, Twitter, YouTube, Google, RSS, podcasts						
Accessibility	Free of charge						
Comments	Approximately 70 percent of the Academy's over 75,000 members are <u>registered dieticians</u> or <u>registered dietician nutritionists</u> and 2 percent are <u>dietetic technicians</u> , <u>registered</u> . The Academy of Nutrition and Dietetics has developed a social media policy for public social media participation.						

# 6.3. Available risk calculators

Calculators related to patient education and decision support in CARRE are listed in the Table 48.

Calculator	Related to	Link	Parameters	Description	Citation
RRT risk	2 and 5 year probability of treated kidney failure (dialysis or transplantation)	http://www.qx md.com/calcul ate- online/nephrol ogy/kidney- failure-risk- equation	Age Sex GFR UACR Calcium Phosphorus Albumin Bicarbonate	The kidney failure risk equation provides the 2 and 5- year probability of treated kidney failure (dialysis or transplantation) for a potential patient with chronic kidney disease (CKD) Stage 3 to 5. Predicted risks may differ from observed risks in clinical populations with lower and higher observed risks than the study population. This risk calculator was developed and validated in two independent populations of patients with CKD referred to nephrologists in Canada. Determining the probability of kidney failure may be useful for patient and provider communication, triage and management of nephrology referrals and timing of dialysis access placement and living related kidney transplant. Prospective trials evaluating the utility of this instrument for clinical decision-making have not yet been performed.	Tangri N, Stevens LA, Griffith J, et al. A predictive model for progression of chronic kidney disease to kidney failure. JAMA. 2011;305(15).
Chronic Kidney Disease (CKD) staging	GFR estimation	http://mdrd.co m/	Creatinine Age Race Gender Cystatin C	4 variable MDRD Study Equation, CKD-EPI Creatinine Equation (2009), CKD-EPI Cystatin C Equation (2012) and CKD-EPI Creatinine-Cystatin C Equation (2012) (with SI Units) using standardized serum creatinine, age, race, gender and serum Cystatin C.	Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF 3rd, Feldman HI, Kusek JW, Eggers P, Van Lente F, Greene T, Coresh J; CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration). A New Equation to Estimate Glomerular Filtration Rate. Ann Intern Med. 2009 May 5;150(9):604-12. Levey AS, Coresh J, Greene T, Marsh J, Stevens LA, Kusek JW, Van Lente F; Chronic

					Kidney Disease Epidemiology Collaboration. Expressing the Modification of Diet in Renal Disease Study Equation for Estimating Glomerular Filtration Rate with Standardized Serum Creatinine Values. Clin Chem. 2007 Apr;53(4):766-72. Epub 2007 Mar 1. Inker LA, Schmid CH, Tighiouart H, Eckfeldt JH, Feldman HI, Greene T, Kusek JW, Manzi J, Van Lente F, Zhang YL, Coresh J, Levey AS; CKD-EPI Investigators. Estimating glomerular filtration rate from serum creatinine and Cystatin C. New Eng J Med 2012 Jul 5;367(1):20-9.
Chronic Kidney Disease (CKD) risk	Risk of developing moderate- severe kidney disease over the next five years	<u>http://www.qki</u> <u>dney.org/</u>	Age Sex Ethnicity Smoking status Systolic blood pressure Comorbidities Body mass index	The QKidney® algorithms are based on routinely collected data from many thousands of GPs across the country who have freely contributed data to the database for medical research. QKidney® has been developed for the UK population, and is intended for use in the UK. All medical decisions need to be taken by a patient in consultation with their doctor. The authors and the sponsors accept no responsibility for clinical use or misuse of this score.	Hippisley-Cox J, Coupland C. Predicting the risk of Chronic Kidney Disease in Men and Women in England and Wales: prospective derivation and external validation of the QKidney® Scores. BMC Family Practice 2010, 11:49.
Heart attack risk calculator	Myocardial infarction (heart attack)	http://www.hea rt.org/HEART ORG/Conditio ns/HeartAttack /HeartAttackTo olsResources/ Heart-Attack- Risk- Assessment_	Gender Age Smoker Family history of heart disease Abdominal obesity High blood	The calculator helps to assess the risk of having a heart attack or dying from coronary heart disease in the next 10 years and find out how improving risk factors for heart attack may reduce the risk.	American Heart Association (AHA)

Heart attack	Myocardial	<u>UCM_303944</u> <u>Article.jsp</u> http://cvdrisk.n	pressure High blood triglycerides Low HDL cholesterol High blood sugar	The calculator helps to predict a person's chance of	Framingham Heart Study
risk calculator	infarction (heart attack)	hlbi.nih.gov/cal culator.asp	Gender Total cholesterol HDL cholesterol Smoker Systolic blood pressure Current use of medications to treat high blood pressure	having a heart attack in the next 10 years.	Taninghan flear oldy
Risk for developing heart disease within the next 10 years calculator	Cardiovascular disease	https://www.ca rdiosmart.org/ Tools/Heart- Disease-Risk- Assessment	Total cholesterol HDL cholesterol LDL cholesterol Triglycerides Systolic blood pressure Diastolic blood pressure Medications Birth date Diabetes Smoker Gender	The calculator is designed to assist patients who have not been diagnosed with heart disease in understanding their risk for developing heart disease within the next 10 years.	Framingham Heart Study
10-year risk of	Cardiovascular	http://www.upt	Age	This calculator may be applied to men who have had	D'Agostino RB Sr, Vasan RS,

developing cardiovascular disease in men	disease	odate.com/con tents/calculato r-10-year-risk- of-developing- cardiovascular -disease-in- men-patient- information?so urce=search r esult&search= calculators&se lectedTitle=10 7~150	Systolic Blood Pressure Total cholesterol HDL cholesterol Use of blood pressure medication Cigarette smoker Diabetes	no prior history of cardiovascular disease to assess 10- year risk of developing cardiovascular disease.	Pencina MJ, et.al. General Cardiovascular Risk Profile for Use in Primary Care. The Framingham Heart Study. Circulation.2008 Jan 22.
10-year risk of developing cardiovascular disease in women	Cardiovascular disease	http://www.upt odate.com/con tents/calculato r-10-year-risk- of-developing- cardiovascular -disease-in- women- patient- information?so urce=search_r esult&search= calculators&se lectedTitle=8~ 150	Age Systolic Blood Pressure Total cholesterol HDL cholesterol Use of blood pressure medication Cigarette smoker Diabetes	This calculator may be applied to women who have had no prior history of cardiovascular disease to assess 10-year risk of developing cardiovascular disease.	D'Agostino RB Sr, Vasan RS, Pencina MJ, et.al. General Cardiovascular Risk Profile for Use in Primary Care. The Framingham Heart Study. Circulation.2008 Jan 22.
Heart disease risk calculator	Cardiovascular disease	http://www.sha pesense.com/f itness- exercise/calcul ators/activity- based-calorie- burn- calculator.aspx	Age Gender Height Weight Race History of conditions and procedures Family history Smoking	The heart disease risk calculator helps to find out the risk of cardiovascular disease.	Created by Mayo Foundation for Medical Education and Research using content from Framingham Heart Study Cardiovascular Disease 10- Year BMI-Based Risk Score Calculator, Framingham Heart Study General Cardiovascular Disease 30-Year Lipid-Based and BMI-Based Calculators, and ACC/AHA Pooled Cohort Equations CV Risk Calculator

			Diabetes Cholesterol Blood pressure Blood pressure medication Physical activity Nutrition		
High blood pressure health risk calculator	Hypertension	http://www.hea rt.org/beatyour risk/en_US/hb pRiskCalc.html ?hasSet=true	Gender Age Tall Weight Systolic blood pressure Diastolic blood pressure Other diseases and conditions	The calculator helps to learn the risk of having a <u>heart</u> <u>attack</u> , a <u>stroke</u> , and developing <u>heart</u> <u>failure</u> and disease according to the blood pressure readings.	American Heart Association (AHA)
Cholesterol calculator	Dyslipidaemia, cardiovascular disease, heart attack, stroke, peripheral artery disease	https://www.ca rdiosmart.org/ Tools/Choleste rol-Calculator	Total cholesterol HDL cholesterol LDL cholesterol Triglycerides	The calculator helps to determine if cholesterol level is correct.	American College of Cardiology Foundation
LDL Cholesterol Calculator	Dyslipidaemia, cardiovascular disease, heart attack, stroke, peripheral artery disease	http://www.ma yoclinic.org/ldl- cholesterol/itt- 20084940	Total cholesterol HDL cholesterol LDL cholesterol Age Gender Blood pressure Smoking Diabetes History of CVD Family history	The LDL cholesterol calculator helps to find out what LDL level should be.	Adapted by Mayo Foundation for Medical Education and Research. Using the National Cholesterol Education Program (NCEP), ATP III Executive Summary, 2001.

Fitness and exercise calculator	Physical activity	http://www.we bmd.com/fitne ss- exercise/healt htool-exercise- calculator	Weight Duration of exercise Type of exercise	The calculator helps to estimate how many calories burn during the workout.	Network of U.S. Board Certified Physicians and Allied Health Professionals
Calories calculator	Physical activity	http://www.bhf. org.uk/heart- health/preventi on/calorie- calculator.aspx	Age Weight Activity Time	The calculator helps to estimate how many calories burn during the physical activity.	British heart foundation
Financial Cost of Smoking Calculator	Smoking	http://www.hea rt.org/HEART ORG/GettingH ealthy/QuitSm oking/Quitting Resources/Fin ancial-Cost-of- Smoking- Calculator_UC M_304171_Art icle.jsp	Number of cigarettes smoked per day Number of cigarettes in a pack Price per pack	The calculator is used to find out how much it costs to smoke.	American Heart Association (AHA)