AMICA
Autonomy Motivation & Individual Self-Management for COPD patients (AMICA)

DELIVERABLE 4
WEARABLE SENSOR SYSTEM

Workpackage WP1 – Sensor technologies and Biomedical Engineering
Nature: Prototype

Abstract
The Autonomy Motivation & Individual Self-Management for COPD patients (AMICA) is aimed at the disease management and medical care of chronic obstructive pulmonary disease (COPD) patients. AMICA is a Research and Development project funded by the states associated to the AAL Joint Programme and by the EC financial contribution (http://www.aal-europe.eu).

AMICA project started April 2009 and lasts for 3 years until April 2012 with a total budget of 2,783,139,48€. Five partners spread across Europe are involved including medical companies and foundations (Vitaphone - Germany, I.S.S- Spain, and the Foundation for Biomedical Research Management- Spain) and Academics (Institute of Communication and Computer Systems from the National Technical University of Athens- Greece, the Engineering School from Cádiz- Spain and the Research Centre for Information Technology from Karlsruhe – Germany).

This report summarizes the most relevant aspects of the prototype developed within the tasks belonging to the Workpackage 1. It contains information about the sensor device to be used at the patient’s homes.

This document has been developed by UCA, FBRMC and FZI.

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Project funded by the states associated to the AAL Joint Programme and by the EC financial contribution (http://www.aal-europe.eu)
Work Package WP1 – Sensor Technologies and Personal Monitoring
Deliverable 4 Wearable Sensor System

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<table>
<thead>
<tr>
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<th>Role within the consortium</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Cádiz (UCA)</td>
<td>Coordinator / ICT and Medical R&amp;D</td>
<td>Spain</td>
</tr>
<tr>
<td>Forschungszentrum Informatik (FZI)</td>
<td>ICT and Economics R&amp;D</td>
<td>Germany</td>
</tr>
<tr>
<td>Institute of Communications and Computer Systems (ICCS)</td>
<td>ICT R&amp;D</td>
<td>Greece</td>
</tr>
<tr>
<td>Vitaphone (VTP)</td>
<td>ICT R&amp;D, Telemedical Service Provider</td>
<td>Germany</td>
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<td>Care Management &amp; Healthcare</td>
<td>Spain</td>
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EXECUTIVE SUMMARY

This report describes the Technical Specification of the AMICA sensor to be used at the patient’s homes. It specifies the technical implementation needed to realize the functionality which has been identified from the objectives of the proposal and also describes to resulting prototype. It builds a basis for the development activities in the upcoming workpackages WP3 and WP4.

This document is structured as follows:

✓ Section 0: Background
✓ Section 1: Telemedicine and ICT oriented to COPD patients
✓ Section 2: Architecture and Functional Specification
✓ Section 3: The StECG Sensor
✓ Section 4: References
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0 BACKGROUND

The purpose of this section is to introduce the:

✓ AMICA Project
✓ Purpose, scope and context of this deliverable
✓ Intended audience for the deliverable
✓ Document Structure
✓ External References

AMICA Project

The Autonomy Motivation & Individual Self-Management for COPD patients (AMICA) is aimed at the disease management and medical care of chronic obstructive pulmonary disease (COPD) patients. AMICA is a Research and Development project co-funded under the Ambient Assisted Living Joint programme as well as its projects members. Its official website is http://www.amica-aal.com.

It is aimed at providing medical management and medical care to patients suffering from Chronic Obstructive Pulmonary Disease (COPD). COPD is a progressive pulmonary disease characterized by reduction in airflow and is not fully reversible. COPD is the major cause of mortality and increased levels of disability, particularly in the elderly. Symptoms vary among individuals and include breathlessness, dyspnea, abnormal sputum and chronic cough. Exposure to tobacco smoke is by far the most important risk factor in the development of COPD and is associated with high levels of morbidity and mortality.

AMICA’S main objective is to develop and assess long-term COPD management solutions based on innovative Information and Communication Technologies (ICT) that:

✓ Allows early detection of COPD exacerbations through the use of a multifunction biomedical system able to yield continuous and sporadic data on heart, breathing and physical activity. This helps to avoid hospitalization and enhances quality of life of elderly COPD patients.
✓ Offers a user-friendly design for the elderly.
✓ Provides remote monitoring and home-based care
✓ Integrates a technical solution with a holistic service approach.
✓ Fosters prevention and self-management through immediate comprehensive feedback and efficient personalized assistance.
✓ Increases levels of therapy compliance providing effective incentives schemes such as health treatments abroad as an added bonus while it reduces public
health care costs and provides business opportunities on the health tourism market.

AMICA project started April 2009 and lasts for 3 years until April 2012 with a total budget of 2.783.139,48 €. Five partners spread across Europe are involved including medical companies and foundations (Vitaphone - Germany, I.S.S- Spain. and the Foundation for Biomedical Research Management- Spain) and Academics (Institute of Communication and Computer Systems from the National Technical University of Athens- Greece, the Engineering School from Cádiz– Spain and the Research Centre for Information Technology from Karlsruhe – Germany).

This report summarizes the most relevant aspects of the prototype developed withing the tasks belonging to the Workpackage 1. It contains information about the sensor device to be used at the patient’s homes.

This document has been developed by UCA.

Deliverable purpose, scope and context

The purpose of the this report is to define how the system functionality identified from the project objectives is going to be realized. The specification will build a sufficient basis to conduct the development activities in future workpackages.

Audience

This report is included within a RESTRICTED deliverable. The intended audience includes:

- Primarily AMICA Partners involved in the implementations to be realized in WP3 and WP4.
- Project partners involved in AMICA WP5 and WP7.

Document Structure

This document is structured as follows:

- **Section 0: Background** - provides background information about the deliverable.

- **Section 1: Telemedicine and TICs oriented to COPD Patients** - provides a general scope of the state of art.

- **Section 2: Architecture and Functional Specification** - This section briefly describes the major findings influencing the technical specification of the AMICA framework.
✓ **Section 3: The StECG sensor**

**Overall Technology Selection** – Within this section the sensor technologies to be used in AMICA are described.

✓ **Section 4: References**

**References**

This document is dependent on the Deliverable 1 "Medical foundations for COPD Disease Management".
1 TELEMEDICINE AND ICT ORIENTED TO COPD PATIENTS

An efficient telemedical system should be able to monitor patients in an easy way, transmit vital signs to a recipient center, and allow for their assessment (a contact net between the patients and the health care staff). The above mentioned characteristics together with a health care education program designed to improve and educate patients on respiratory techniques, therapy compliance, balanced diet and monitored respiratory rehabilitation and physical exercise program will help reduce hospital admissions and provide advanced COPD patients, who consume large amounts of resources, with greater individual skills, autonomy and motivation.

Telemedical treatment of COPD should be approached from a completely different perspective than cardiovascular disorders [1-4], which are very common within the context of e-health. While the latter requires well defined variables - electrocardiogram segments mainly- to be efficient, the approach to a chronic disorder characterized by its great morbidity though not by a sudden onset, such as COPD, is more complex. The pathogenesis of COPD is not easy to determine, though in a considerable percentage of cases the disease might be of a viral nature. The main symptom of an acute exacerbation of COPD [5] is increased breathlessness, which is often accompanied by an increased cough and sputum production, change in the color and/or thickness of the sputum, wheezing, chest tightness and fever. Once these symptoms have been determined, a procedure framework should be established to allow to:

1. Keep abreast of exacerbations, by means of corrective measures (medication, pulmonary rehabilitation therapies,...) that enhance the patient’s health status, thus avoiding hospital admissions with the resulting positive effect that corrective measures imply: first, on the patient’s quality of life and , second, on the health system in terms of cost and burden associated with the disease.
2. As for other medical platforms, provide educational support to patients, both for better disease knowledge and management and for the promotion of a series of social behavior patterns due to the great psychological impact exacerbations have on their health [6].

Such a framework should be implemented by considering the monitoring technologies, the educational and social motivation aspects, a patient oriented telemedical platform, usability tests and service and business models. These are basically the objectives of the AMICA AAL project.

1.1 Monitoring technologies and early detection of COPD exacerbations

To date, spirometry is the golden standard in the management of COPD patients, but patients’ perception of their lung capacity does not always match spirometry results. In some cases, the false-positive and false-negative rates in a primary care setting might be quite high. The main reason for this is the misapplication of accurate instruments.
Almost all currently available spirometers meet the American Thoracic Society recommendations for accuracy and reproducibility, but these valuable instruments are often misused in clinical settings [7][8].

Thus, to solve this lack of clinical reliability, AMICA propose the using of simple sensors. Apart from recording breathing, sensors might also capture other physiological parameters: heart rate, physical activity and tracheal sounds. The collected data might be processed in a microprocessor-based system to extract and transmit those variables and physiological parameters. Early detection of changes in these variables should allow for early treatment of COPD exacerbations avoiding the feared hospital incomings.

The Deliverable 1 (WorkPackage 2), “Medical Foundations for Prevention, Diagnosis & Therapy” describes the guiding symptoms to be taken into account for the detection of exacerbations:

- **Guiding symptoms of acute exacerbations**
  - Increasing dyspnoea accompanied by increased coughing, increase of quantity and viscosity of the sputum and / or yellow-green change of colour.
  - Chest tightness
  - Occasionally fever
  - Unspecific: blur of consciousness right up to coma, insomnia, defatigation, depressions

- **Guiding symptoms of heavy acute exacerbations**
  - Newly occurring or progredient central cyanosis
  - Peripheral oedemata
  - Help of the „accessory respiratory muscles “ within inspiration process
  - Haemodynamical instability
  - Peak-Flow-figure<100l/min
  - FEV1<1l

- **Life-threatening condition**
  - At pO2<50 mmHg, pCO2>70mmHg, pH<7,3

It also describes an action plan to enhance early detection and management of exacerbations based on criteria for stationary / intensive medical treatment, as detailed in Table I, where the implementation within the AMICA system is described.
1.2 A state-of-art and patient-oriented Telemedical platform

As discussed, many research projects have been developed telemedical platforms in the last few years [1] [9-14]. These projects were based on wireless sensor networks and commercial off-the-shelf mobile computing devices such as PDAs and mobile phones. While wireless medical sensors proved to be useful in many applications, the use of personal mobile devices as a base station and user interfaces poses many difficulties. Consequently, these devices are generally not well accepted in the “real-world” medical applications [1] [15-16]. From our point of view, this is mainly because the human machine interface (HMI) mechanisms of mobile devices are not adapted to the needs and requirements of patients, which represents a big obstacle especially for elderly people as end-users. Another difficulty is the short product life-cycle of consumer devices, which poses a big challenge to telemedical system suppliers due to the high software maintenance efforts needed associated to these devices.

AMICA tries to focus on an optimal approach that could help overcome these problems by implementing a dedicated mobile device (DmD), which might be especially adapted to the disease management application area and to the user-interface needs of elderly people. Similar approaches, such as special mobile phones for elderly people, have shown high market acceptance.

<table>
<thead>
<tr>
<th>STAT. / INTENSIVE TREATMENT</th>
<th>IMPLEMENTATION WITHIN THE AMICA SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute chest tightness</td>
<td>Questionnaire, StECG sensor</td>
</tr>
<tr>
<td>Bad state of health</td>
<td>Questionnaire, pulse oximeter</td>
</tr>
<tr>
<td>Rapid progression of symptoms</td>
<td>Vital parameter-history</td>
</tr>
<tr>
<td>Blur of consciousness</td>
<td>Questionnaire, pulse oximeter, speech recognition</td>
</tr>
<tr>
<td>Edema and/or a central cyanosis</td>
<td>Pulse oximeter, Touch-test in Questionnaire</td>
</tr>
<tr>
<td>Lacking talk about the initial therapy</td>
<td>Vital parameter-History</td>
</tr>
<tr>
<td>Arrhythmias detection, lung sounds changes</td>
<td>StECG sensor</td>
</tr>
<tr>
<td>Significant comorbid conditions</td>
<td>Anamnesis / Questionnaire</td>
</tr>
<tr>
<td>Higher life span</td>
<td>Questionnaire</td>
</tr>
<tr>
<td>Insufficient domestic care</td>
<td>Questionnaire</td>
</tr>
</tbody>
</table>

Table I. Symptoms for early detection of exacerbations and the implementation within AMICA.
The system proposed in AMICA for COPD management is relatively simple from the point of view of telemedical protocols. The adopted protocol is based on the “STORE AND FORWARD” type [17] whereby the patient information is first transmitted and the expert opinion is given afterwards. The workflow will be as follows:

1. Acquisition: The patient information (demographic details, reports, biosignals, etc.) is obtained.
2. Storage: The above mentioned information that has been acquired is then stored.
3. Transmission: The patient information is transmitted to the Telemedicine Center.
4. Storage: The patient information is then stored in the Telemedicine database.

During the consultation the specialist at the Specialty Center gives his opinion after going through the patient information sent by the DmD.
2 ARCHITECTURE AND FUNCTIONAL SPECIFICATION

Work package I focus on the following objectives:

1. Development, test and evaluation of an innovative personal monitoring system for COPD patients
2. Design of Biosignal processing algorithms in order to extract information about the patient’s health status for diagnosis and therapy control

These objectives define one further step towards the translation of the requirements and envisioned algorithms and data structures into an articulated software/hardware platform. Figure 1 gives an overview of the components identified in the overall AMICA architecture.

Figure 1: System overview. EPR= Electronic Patient Record

The telemedical system will then consist of the following modules:

2.1 Patient data Server
The patient data server will be exhaustively described in the Deliverable 9 (“Telemedical Platform”).

2.2 User sensors
The user will be capable to employ several sensors (StECG, spirometers, SpO2, scale,...) for biomedical monitoring of the adventitious respiratory sounds and other variables
relevant in COPD. The information will be converted into packets and transmitted to the server via the DmD using TCP/IP and/or UDP protocols. The patient data server, settled in the management center (Hospital), will store data in a relational database. Then, health care providers will be able to monitor their patients using the server application. Signals and reports may be exported to files or printed.

Most of the existing patient monitors have reliable signal acquisition capabilities. Nevertheless, this kind of equipment is not usually developed to aim at connectivity. Transmission between the sensor device and the DmD will be wireless for a better user comfort. First stages of development will use cable as physical medium to transmit signals but the final release will use wireless transmission. It is essential to remark that the main objective in this report deal with the StECG sensor. Integration of SpO2 sensors, scales or spirometers is out of the scope of this study.

2.3 Network

Patient data server and user terminals must be connected through the IP-based telemedicine network. The Hospital or management center will be connected via a dedicated line, and the patient’s home via HSDPA/3G technology. Security must be a prime concern. Different security needs should be identified within the system, depending on the user, content of information exchanged, type of access, and location. Authentication profiles (PKI certificate, tokens,...) and transport security (SSL, VPN, ...) need to be defined as well. Deliverable 3 will take into account security issues.
3 THE StECG SENSOR

3.1 Relevance of lung sounds and ECG in COPD

Lung sounds and EKG provide important information in the diagnosis and monitoring of the clinical course of patients with lung disorders.

It is likely that emphysema produces different physical signs than does chronic bronchitis, but most patients present with varying degrees of both processes. Accordingly, the clinician usually encounters a mixture of findings in patients who have both bronchitis and emphysema, the syndrome of chronic obstructive pulmonary disease. Lung sounds and heart activity are primary indicators to detect COPD exacerbations.

3.1.1 Lung Sounds

In COPD, the breath sounds are decreased in intensity. Wheezing is common, particularly at end-expiration. It may be brought out by a forced maximum expiratory effort if no wheezing is heard with quiet breathing. Rhonchi are also common and generally clear or change after coughing. Basilar crackles may be present and can be either fine or coarse in character, early inspiratory in timing, and few in number. Expiration is prolonged relative to inspiration, and pursed-lip breathing may be observed. The percussion note is characteristically hyper-resonant.

In the early stages of COPD, physical assessment may be entirely normal except during episodes of exacerbation, when wheezing or rhonchi may be present. The diagnosis of COPD is highly depending on which guidelines are used for defining the disease. If FVC and not the best of SVC and FVC is used when defining COPD the diagnosis will be missed in a substantial number of patients. Spirometry is the most reproducible, standardized and objective way of measuring airflow limitation and FEV$_1$ is the variable most closely associated with prognosis. However, it should be noted that patients with an FEV1 > 80% predicted, although within the normal range, may have airflow limitation (FEV1/FVC ratio < 70%).

Anyway, diagnosis is not the aim of the project but early detection of exacerbations. In this sense the periodic acquisition and analysis of lung sounds is very valuable to predict exacerbations just because it reproduces the medical procedure during a patient revision. Thus, the implementation of a remote daily auscultation at patient’s homes (performed by patients themselves) within a telemedical platform is one of the objectives in AMICA. The early detection of adventitious sounds could alert the system and the specialists in charge of the patient’s medical assistance.

Two types of transducers are in common use for lung sound recording and research: electret microphones with coupling chamber and the accelerometers. Small electret microphones are widely available for speech and music recording. When coupled to the skin by a sealed chamber, similar to a stethoscope bell, this type of microphone is a
sensitive lung sound transducer. Different sizes and shapes of coupling chambers have been found to affect the overall frequency response of this coupling. Those arrangements with smaller, conically shaped chambers are more sensitive to higher lung sound frequencies (10, 11), but also highly susceptible to ambient noise. Contact accelerometers are also popular in lung sound research and can be calibrated on a vibration table so their output is quantified. However, they are typically more expensive than electret microphones, are often fragile, and may exhibit internal resonances near the lung sound frequencies of interest. Those are the mainly reasons why after intensively testing of accelerometer, the using of electrets condenser microphones has been adopted.

3.1.2 ECG: tachycardia and arrhythmias

Patients with acute exacerbations usually have combinations of increased work of breathing, low O2 saturations on oximetry, diaphoresis, anxiety, cyanosis and tachycardia. Thus, the recording of a basic short-time ECG may be valuable to measure deviation of heart rate over the baseline of every patient at rest.

3.2 Description of the sensor

The relevance of ECG and LS in the detection of COPD exacerbations drives to the design of a multifunctional equipment able to easy acquire these data within a single user test. Thus, a microphone and ECG based device has been designed to fulfill such a purpose. The device, named StECG, is basically depicted in Figure 2.

The prototype technical specifications are following described.

3.2.1 Microphone

Previously, the using of ECM (electret condenser microphones) has been proposed. An ECM is an audio-electric converting device, whose audio pickup section has a structure of a condenser consisting of a diaphragm and a back plate opposite thereto. The motion of the diaphragm by sound is picked up as a variation of capacitance between the diaphragm and the back plate.

Parameters

Three are the basic parameters to define an ECM:

1. **Sensitivity** is defined as the output voltage for a specified acoustic stimulus and load condition. It is usually expressed in dBV/pa (dBV/10μbar). In the case of dynamic types it is expressed as the open circuit voltage appearing at the output terminals. In the case of electret type it is expressed with a specified resistive load and supply voltage since the output resistance tends towards constant current characteristic.
2. The **output impedance** represents the internal electric resistance within a microphone as seen from the side of output terminals of the microphone. In the case of ECMs, the effective output resistance is determined mainly by the value of load resistance. It can be made higher or lower by the value of load resistance with a corresponding change in sensitivity.

3. The **frequency response** of a microphone is the data indicating which frequency range, from the lower to the higher range, the microphone has a certain sensitivity. In other words, it is the frequency range within which the microphone can receive sound. It is expressed as 50 Hz-15000 Hz.

Table 2 illustrates the summary of recommendations for the case of lung sounds acquisitions with an electric condenser microphone.

<table>
<thead>
<tr>
<th>Capsule</th>
<th>Condenser electret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directivity</td>
<td>Omnidirectional</td>
</tr>
<tr>
<td>Frequency response</td>
<td>Flat in the range 50-18,000 Hz</td>
</tr>
<tr>
<td>Sensibility</td>
<td>&gt; 50 dB (V/Pa) at 1 KHz</td>
</tr>
<tr>
<td>Signal to Noise Ratio</td>
<td>&gt; 60 dB</td>
</tr>
<tr>
<td>Output impedance</td>
<td>1.000 Ohm</td>
</tr>
<tr>
<td>Power voltage</td>
<td>1.5 V (LR-44)</td>
</tr>
</tbody>
</table>

Table II. ECM technical recommendations for LS recording
The lung sounds recordings performed with COPD patients at the Hospital used FONESTAR FCM 400 microphone. Some commercial devices close to recommendations are included in Table III.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Frequency Band</th>
<th>Sensibility</th>
<th>Impedance</th>
<th>Power</th>
<th>Omnidirectional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ariston</td>
<td>CME-6</td>
<td>100 Hz - 8 kHz</td>
<td>62 dB</td>
<td>2k</td>
<td>1.5 - 10 V</td>
<td>NO</td>
</tr>
<tr>
<td>Ariston</td>
<td>CME-7</td>
<td>50 Hz - 8 kHz</td>
<td>64 dB</td>
<td>2k</td>
<td>1.5 - 10 V</td>
<td>SI</td>
</tr>
<tr>
<td>Ariston</td>
<td>CME-12</td>
<td>50 Hz - 13 kHz</td>
<td>54 dB</td>
<td>1k</td>
<td>1.5 - 10 V</td>
<td>SI</td>
</tr>
<tr>
<td>Ariston</td>
<td>CME-16</td>
<td>50 Hz - 13 kHz</td>
<td>67 dB</td>
<td>1k</td>
<td>1.5 - 10 V</td>
<td>SI</td>
</tr>
<tr>
<td>Ariston</td>
<td>CME-20C</td>
<td>50 Hz - 13 kHz</td>
<td>64 dB</td>
<td>1k</td>
<td>1.5 - 10 V</td>
<td>SI</td>
</tr>
<tr>
<td>Star Micronics</td>
<td>MAA-03A</td>
<td>50 Hz - 10 kHz</td>
<td>44 dB</td>
<td>2.2k</td>
<td>1 - 10 V</td>
<td>SI</td>
</tr>
<tr>
<td>Fonestar</td>
<td>2214</td>
<td>50 Hz - 10 kHz</td>
<td>40 dB</td>
<td>300 - 5k</td>
<td>1.5 - 15 V</td>
<td>SI</td>
</tr>
<tr>
<td>Fonestar</td>
<td>2217</td>
<td>50 Hz - 16 kHz</td>
<td>44 dB</td>
<td>150 - 5k</td>
<td>1.5 - 15 V</td>
<td>SI</td>
</tr>
<tr>
<td>Damnike</td>
<td>ECM 60A</td>
<td>0.3 Hz - 18 kHz</td>
<td>50 dB</td>
<td>300 - 5k</td>
<td>1.5 - 10 V</td>
<td>SI</td>
</tr>
<tr>
<td>Damnike</td>
<td>ECM 10A</td>
<td>0.3 Hz - 18 kHz</td>
<td>55 dB</td>
<td>300 - 5k</td>
<td>1.5 - 10 V</td>
<td>SI</td>
</tr>
</tbody>
</table>

Table III. ECM commercial devices with acceptable

Selected ECM

The selected microphone is STAR MICRONICS - MAA-03A-L60-B - MICROPHONE, -44DB, OMNI. It is a Back Electret Condenser omnidirectional Microphone

The technical specifications can be appreciated in Table III. As part of the design, a silicone diaphragm will be placed (for vented adherence to patient’s skin). The air chamber will be conic shaped.

Environmental microphone

A second microphone is placed far away from the head, in order to record environmental noises. This will allow to clean the lung sounds signal (removing voices, sounds from motors, heart sounds,...) by using an adaptative filter stage.

3.2.2 Three Leads ECG

ECG signal characteristics

Figure 3 shows three bandwidths used for different applications in electrocardiography. The clinical bandwidth used for recording the standard 12-lead ECG is 0.05–100Hz. For monitoring applications, such as for intensive care patients and for ambulatory patients, the bandwidth is restricted to 0.5–50Hz. In these environments, rhythm disturbances (i.e., arrhythmias) are principally of interest rather than subtle morphological changes in the waveforms. Thus the restricted bandwidth attenuates the higher frequency noise caused by muscle contractions (electromyographic or EMG noise) and the lower frequency noise caused by motion of the electrodes (baseline changes). A third bandwidth used for heart rate meters...
(cardiotachometers) maximizes the signal to noise ratio (SNR) for detecting the QRS complex. Such a filter passes the frequencies of the QRS complex while rejecting noise including non-QRS waves in the signal such as the P and T waves. This filter helps to detect the QRS complexes but distorts the ECG so much that the appearance of the filtered signal is not clinically acceptable. One other application not shown extends the bandwidth up to 500 Hz in order to measure late potentials. These are small higher-frequency events that occur in the ECG following the QRS complex. The peak amplitude of an ECG signal is in the range of 1 mV, so an ECG amplifier typically has a gain of about 1000 in order to bring the peak signal into a range of about 1 V.

![Figure 3. Bandwidths used in electrocardiography. The standard clinical bandwidth for the 12-lead clinical ECG is 0.05–100 Hz. Monitoring systems typically use a bandwidth of 0.5–50 Hz. Cardiotachometers for heart rate determination of subjects with predominantly normal beats use a simple bandpass filter centered at 17 Hz and with a Q of about 3 or 4.](image)

**Instrumentation**

The general instrumentation requirements for the ECG have been addressed by professional societies through the years. Briefly, they recommend a system bandwidth between 0.05 and 150 Hz. Of great importance in ECG diagnosis is the low-frequency response of the system, because shifts in some of the low-frequency regions, e.g., the ST segment, have critical diagnosis value. While the heart rate may only have a 1-Hz fundamental frequency, the phase responses of typical analog high-pass filters are such that the system corner frequency must be much smaller than the 3-dB corner frequency where only the amplitude response is considered. The system gain depends on the total system design. The typical ECG amplitude is ±2 mV, and if A/D conversion is used in a digital system, the enough gain to span the full range of the A/D converter is appropriate.

**Practical Electrodes for Biomedical Measurements**

The depolarisation of muscles and nerves, which respectively cause contraction and the passage of information, is associated with the movement of chemicals across a semi-permeable membrane. This ionic movement causes the generation of an action potential. If two electrodes are placed near to an excitable cell then when the cell is depolarised a potential is developed between the two electrodes. Biopotential recording effectively measures the potential produced by cell depolarisation or the electrical activity of nerves and muscles. Essentially, cell membrane depolarisation is...
identical in nerves and muscles. The amplitude of the response is far greater in muscles: it is in the order of 1000 times greater from heart muscle contraction than through a neural nerve impulse.

The measurement of the contraction of the heart, which can be viewed as a special type of muscle, is called Electrocardiography (ECG).

The patient ECG interface is formed by a special bioelectrode that converts the ionic current flow of the body to the electron flow of the metallic wire. These electrodes typically rely on a chemical paste or gel with a high ionic concentration. This acts as the transducer at the tissue-electrode interface. For short-term applications, silver-coated suction electrodes or “sticky” metallic foil electrodes are used. Long-term recordings, such as for the monitored patient, require a stable electrode-tissue interface, and special adhesive tape material surrounds the gel and an Ag+/Ag+Cl– electrode.

Because of the project requirements (short-time recordings), metallic foil electrodes will be used. The basic metal plate electrode consists of a metallic conductor in contact with the skin. A thin layer of an electrolyte gel between the metal and the skin may be suggested to use to get a better contact. Metals commonly used for this type of electrode include German silver (a nickel-silver alloy) or copper.

**Biopotential Recording Systems**

A block diagram of a typical biopotential recording system is shown in Figure 5. To perform a biopotential recording, electrodes or leads are attached to the patient and then connected to a high gain differential amplifier with good common mode rejection. The system also incorporates low pass filtering stage. The LPF cut-off frequency is set to 40 Hz to remove the higher frequency noise (including the 50 Hz AC interference although final prototypes will be operated with batteries). As biopotential recording necessitates that a low impedance connection is made to the patient, patient safety has to be assured. This is achieved by isolating the pre-amplifier stages.
The input preamplifier stage should have very high input impedance and a high common-mode-rejection ratio (CMRR).

We are surrounded by power lines and equipment operating from a mains supply. Power lines operate typically at levels of hundreds of volts. The patient standing in a room is capacitively coupled to the power lines. A biopotential measurement, such as an ECG, is then susceptible to a significant signal due to this coupling. As the biopotential is of the order of 1mV the capacitive interference may completely mask the biopotential signal. Differential amplifiers which reject common mode signals will facilitate the measurement in the presence of large interference signals.

The ratio of the amplification of the required differential signal to the amplification of common mode signal is termed the common mode rejection ratio. For biopotential recording a high common mode rejection ratio is required. The common mode rejection ratio for biopotential recording apparatus is normally between 80 and 120 dB for ECG measurements. The impedance of the amplifier must be large so that the biopotential is developed across the input of the amplifier and not across the patient electrode interface.

The goal of the ECG amplifier is to produce a signal that is usable by the ADC. Several stages build the whole bioamplifier, as depicted in Figure 6. The first stage is the instrumentation amplifier. The inputs are the two signals from electrodes. Based on the properties of Common Mode Rejection (CMR), as before detailed, any major differences between the two signals are rejected, resulting in a much cleaner signal.

The second stage of the ECG circuitry is the high pass filter. This filter only allows signals above a certain frequency to pass through. Typical cut-off frequency is 0.2Hz. This will help prevent any low-frequency noise from disrupting the signal, such as DC voltages and skin capacitance effects.

The third stage is a high gain isolation amplifier. This just provides a small amount of gain, in order to get the signal to a useable level. The circuitry of this block also increase safety by preventing fault currents from flowing through the body by way of a ground-referenced biopotential electrode containing a barrier to the passage of current from the power line. For example, if the patient came in contact with a 230V
line, this barrier would prevent dangerous currents from flowing from the patient through the amplifier to the ground of the DmD in the first stage of the design (data transmission by cable).

The final stage of the ECG circuitry is the Low Pass Filter. This filter prevents any higher frequency noise from interfering with the signal. Because of the purposing of the circuit is mainly the heart rate monitoring, cutoff frequency of 100 Hz is more than enough.

3.3 Ergonomy

Ergonomy studies drove to the final design, showed in figure 7.

3.4 Data Transmission

Final design will use wireless transmission (BTE 4.0) to fullfil the Continua Health Alliance specifications. The first approach to design will use cable transmission using the USB port in the base station. ECG and sounds (signal and environmental sounds) are multiplexed to build a data frame. Reception then needs a demultiplexion software utility.

In the ADC end, a converter with 12 bits for sounds and 224 bits for ECG are used.

3.4.1. Sampling rates

Sampling rates are defined according to previously detailed information (Table
3.5 Power

The device will operate by recharging batteries. No external metal contacts will be placed. The base of the device will have an anchor point to the charger, so that the metal contacts for charging are concealed. First prototype is powered by using the USB port (5V).
4 REFERENCES


