AMON: A Wearable Multiparameter Medical Monitoring and Alert System

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***Abstract*—This paper describes an advanced care and alert portable telemedical monitor (AMON), a wearable medical monitoring and alert system targeting high-risk cardiac/respiratory patients. The system includes continuous collection and evaluation of multiple vital signs, intelligent multiparameter medical emergency detection, and a cellular connection to a medical center. By integrating the whole system in an unobtrusive, wrist-worn enclosure and applying aggressive low-power design techniques, continuous long-term monitoring can be performed without interfering with the patients' everyday activities and without restricting their mobility.**

In the first two and a half years of this EU IST sponsored project, the AMON consortium has designed, implemented, and tested the described wrist-worn device, a communication link, and a comprehensive medical center software package.

The performance of the system has been validated by a medical study with a set of 33 subjects.

The paper describes the main concepts behind the AMON system and presents details of the individual subsystems and solutions as well as the results of the medical validation.

***Index Terms*—Medical device, multiparameter, telemedicine, validation, wearable, wrist-worn.**

I. Introduction

WEARABLE systems can be broadly defined as mobile electronic devices that can be unobtrusively embedded in the user's outfit as part of the clothing or an accessory. In particular, unlike conventional mobile systems, they can be operational and accessed without or with very little hindrance to user activity [1], [2]. Today, wearable systems range from microsensors, seamlessly integrated in textiles through consumer electronics, embedded in fashionable clothes and computerized watches to belt-worn personal computers (PCs) with a head-mounted display.

One obvious application of wearable systems is the monitoring of physiological parameters in a mobile environment. In this context, devices targeting the sport and recreational market have been very successful. However, the majority of such recreational devices are not suitable for medical monitoring of high-risk patients. Those devices that have been qualified for medical use are usually fairly simple, measuring just one or two parameters and providing little or no online analysis.

The advanced care and alert portable telemedical monitor (AMON) project—financed by the EU FP5 IST program—takes this idea a step further, aiming at continuous medical monitoring for high-risk cardiac/respiratory patients. This includes continuous collection and evaluation of multiple vital signs, intelligent multiparameter medical emergency detection, and a cellular connection to a telemedicine center (TMC). The idea is that by using an unobtrusive wrist-worn device, monitoring can be performed without interfering with the patients' everyday activities and without restricting their mobility. Thus, people currently confined to the hospital or their homes can lead normal lives while knowing that any medical problems will be detected in time and help will be dispatched. Additionally, physicians are provided with a greater level of information about a patient's condition—from a natural setting—thus enabling them to better tailor treatment.

Mobile monitoring of physiological parameters has been studied by many research groups, e.g., [3] and [4]. For data acquisition, personal Holter monitors are often used, e.g., for electrocardiogram (ECG) and blood pressure.

For one or two parameter measuring, there are several devices commercially available: Agilent, Phillips, and Nellcor all produce handheld pulse oximeters for noninvasive monitoring of blood oxygen saturation and pulse (SpO_2). For blood pressure, Omron produces a range of portable wrist devices.[1]

For the wellness and lifestyle market, there are several products. The chest-worn Polar can measure heart rate, but provides no further information about ECG, such as QRS or QT.[2] The SenseWear from BodyMedia measures activity, temperature parameters, and galvanic skin response. An additional chest-worn sensor for heart rate measurement can be attached.[3]

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[1]Omron Corporation. [Online]. Available: http://www.omron.com

[2]Polar heart rate monitors. [Online]. Available: http://www.polar.fi/

[3]Bodymedia, Inc. [Online]. Available: http://www.bodymedia.com/

The University of Alabama has developed a wearable ECG monitor with real-time feedback to the user [5]. Other sensors can be integrated using a wireless body area network of intelligent sensors [6], but the system contains multiple sensors that are not integrated into a single device. Other multiparameter logging devices, such as Escort Guardian[4] or Micropaq,[5] are also not integrated and have only standard configuration.

Several research groups have developed portable medical devices for home care, which transmit measurements without analysis to a TMC [7]–[9]. Other groups use monitoring devices to understand the reaction of the human body to stress [10] or to improve the recovery process, e.g., from strokes [11]. However, the analysis performed by these is often performed offline at the TMC.

Compared to the above-mentioned projects, the AMON system has several unique features.

1) *Multiparameter Monitoring*: The AMON system is capable of measuring blood pressure, SpO_2, and a one lead ECG, all in a single device. It has an interface to additional external sensors including a full 12 lead ECG. At the time of writing, there are currently no handheld or portable devices which combine all of these measurements.
2) *Activity Recognition*: Using a two-axis acceleration sensor integrated in the system, AMON is capable of detecting the level of user activity and correlating it with the vital signs.
3) *Online Analysis and Emergency Detection*: The wrist--worn device can perform an analysis of all measurements online, presenting them in appropriate form to both wearer and remote TMC. For emergency detection, the analysis can incorporate patients profile and activity information to reduce the number of false alarms.
4) *Flexible Communication Interface*: The cellular connection to the TMC features a flexible communication channel that can use a direct connection as well as short message system (SMS) services. It can also be easily extended to incorporate a transmission control protocol (TCP)/Internet protocol (IP)-based link.
5) *All-in-One Wrist-Worn System*: The AMON system combines all sensors, communication, and processing devices in a single ergonomic wrist-worn enclosure. The integration in one device has the disadvantage of making the signal acquisition, in particular pulse and ECG, harder as compared to distributed systems that place sensors (e.g., ECG electrodes) on several specific body locations. However, for the envisioned target group and application, such "all-in-one design" is essential. It must be assumed that many in the target group are technology averse and possibly have some cognitive impairment (e.g., forgetfulness). On the other hand, the system must be worn on a daily basis and be put on without assistance. Thus, it is not acceptable to have the user put on multiple devices, at different exactly defined body locations.

   The integration of all components in a wrist-worn enclosure and the derivation of vital signs from wrist-based sensors is one of the main contributions of AMON.

[4]Escort Guardian, Invivo Research, Inc. [Online]. Available: http://www.invivoresearch.com/

[5]Micropaq, Wellch Allyn, Inc. [Online]. Available: http://www.monitoring.welchallyn.com/

Fig. 1. AMON prototype.

In order to address the potential for AMON as a medical device—as opposed to merely a lifestyle product—a clinical validation was performed. Although the first AMON prototypes have varying degrees of success in achieving medical accuracy on all measurement combinations, our results clearly demonstrate the feasibility of the concept and solutions to the key technological and scientific issues.

The remainder of the paper is divided as follows: Section II gives an overview of the system; Section III describes the sensor system and the processing algorithms; and Section IV describes the data processing and communication hardware in the wrist unit and at the TMC. We then present the results of the first medical trials and our conclusions in Sections V and VI.

II. System Overview

The AMON System comprises two separate parts: a wrist-worn unit (Fig. 1) and a stationary unit at the TMC (Fig. 2).

Key innovations of the wrist-worn part are as follows: the integration of multiple medical monitors and evaluation software in a single device; the nonstandard placement of measurement sensors; and miniaturization to a level where the device is wearable at the wrist. In addition, mobile communication capability is integrated in the device in the form of an on-board global system for mobile communication (GSM) transceiver. The tranceiver enables data exchange with the medical center.

At the TMC, incoming medical data from wrist-worn units is collected and processed by trained medical personnel. This side of the system is based on a JAVA server platform and a windows workstation connected to a GSM/universal mobile telecommunications systems (UMTS) transceiver. The software allows authorized personnel to securely access medical records and details of a patient in addition to the incoming data from the wrist-worn units. It allows measurement requests to be made direct from the TMC; additionally, a provision is made for direct communication with patients.

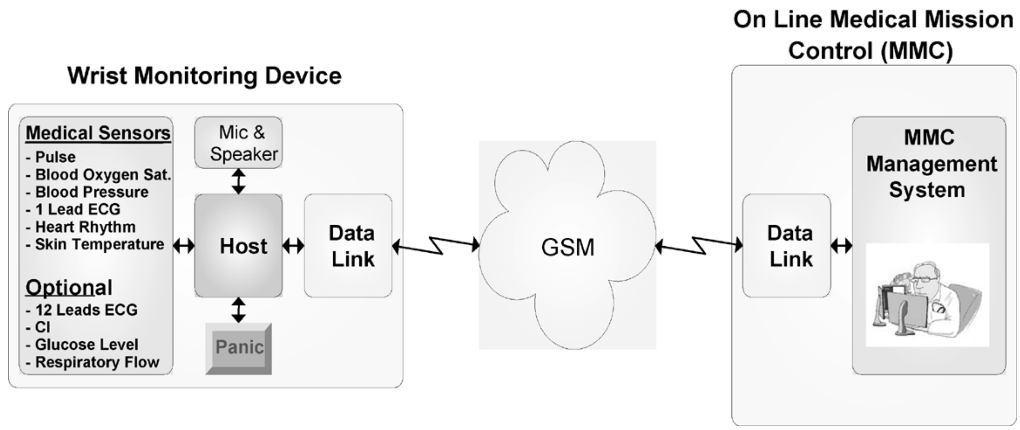

Fig. 2. System overview: AMON; wrist-worn medical device with GSM/UMTS link to the TMC.

AMON monitors pulse, oxygen saturation (SpO_2), skin temperature, and activity via acceleration continuously. Continuously in our medical application means for SpO_2 30 s of measurement every 2 min and every 2 min a temperature reading. Blood pressure and one lead ECG (30 s of raw data) is measured three times a day or on request by the user or the TMC. The data is analyzed on-device after every measurement. The analysis includes all digital signal processing needs for signal enhancement (e.g., filtering), all computation required to convert the measured values into medical values, and initial evaluation of those values.

The main conversion algorithms [see Section III] include the computation of blood pressure from the pressure sensor signal and the derivation of the QRS width, RR distance, and QT interval from the ECG signal.

The initial analysis starts with a comparison of the pulse and oxygen saturation with predefined patient-specific values. Based on the results of this analysis, three different scenarios are possible.

- Everything ok: Wearer is informed that all measurements are fine.
- Parameter out of range: A remeasurement is performed. If the outcome is the same as before, the user is informed and additional measurements are required. The wrist-worn device determines the type and initiates the measurement. The type of measurement includes SpO_2, blood pressure, and ECG. Taking into account combined results of all measurements, the system then decides whether to alert the TMC or not.
- More than one parameter out of range: The data is automatically sent to the TMC, where it triggers an alarm. The medical personnel then performs a detailed analysis of all data rechecking the automatic evaluation. Depending on TMC analysis of this data, further steps are taken: In a nonlife-threatening emergency situation, perhaps requiring modification to treatment or further tests, the patient is referred to his usual physician; if a life-threatening situation is detected, the TMC can immediately organize prehospital care and transportation.

In normal mode (everything ok) the data (raw data and extracted medical values) is transmitted to the TMC three times a day. The center will recheck the measurements; the higher computation power and storage capacity afforded by the TMC is used for more powerful data analysis [see Section IV-C].

In all cases, the patient is informed as to their own status and that of the device. In the event of a failure to initiate communication with the TMC, the user is informed appropriately. In noncritical situations, the results can be stored (up to four days of data) on-device and sent at such a time as communication is restored. The device will periodically attempt to regain communication throughout any down time.

The TMC should be able to cope with multiple remote devices simultaneously. In the event of an abnormal reading, communication should be immediate. Of course this is subject to availability of the GSM connection, and for this reason, users of the system should be instructed, prior to being given the device, to remain within areas with good coverage.

III. Sensors and Algorithms

For the designated target group of cardiac and respiratory patients, the key parameters that need to be monitored are pulse, oxygen saturation (SpO_2), blood pressure, and ECG. Additionally, it is advantageous to have some information about the level of physical activity. This section describes the sensors and the signal processing algorithms used in the AMON system to derive the above information.

The main challenges faced by the design at this stage was the ability to derive all the above information from wrist-worn sensors only and the need to keep the size and the power consumption to a minimum.

A. SPO Sensor

The measurement by pulse oximeter is based on the absorption of two wavelengths through a pulsatory arteriolar flow. Arterial saturation in oxygen and pulse are assessed by comparing the changes of each wavelength during one pulsation. The sensors are either clippers at the tip of fingers or adhesive. There are also reflectance sensors that can be placed on the forehead in front of the temporal artery or that can be put on the sternum. The principle is the same and is based on the absorption of two wavelengths cast and reflected by an arteriolar flow [12], [13].

The AMON device contains a reflectance sensor placed on the top of the wrist (Fig. 3). It uses two wavelengths, one at

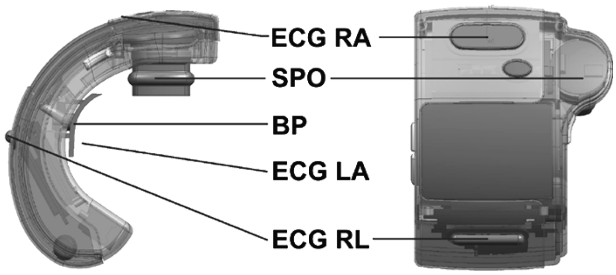

Fig. 3. AMON sensors: SpO_2, one lead ECG (RA, LA, RL), blood pressure (pressure, pump, and valve), acceleration (not shown), and temperature (not shown).

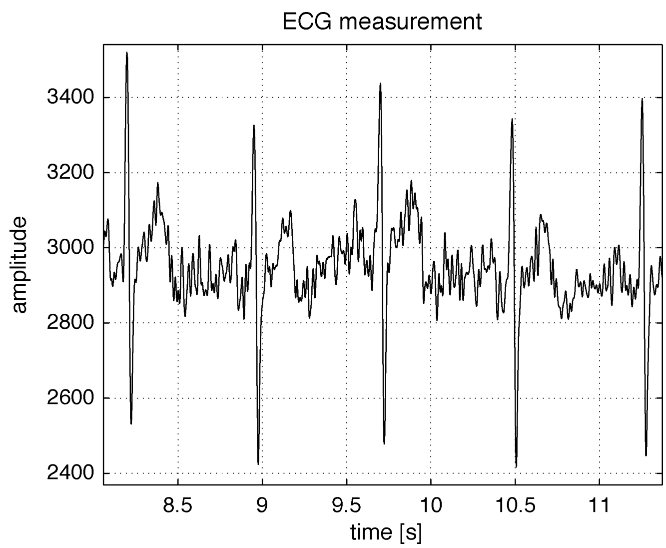

Fig. 4. AMON one lead ECG sample measurement: A digital bandpass filter [0.015 40]Hz has been applied to reduce noise. Heart rate, QT interval and QRS duration can be detected.

660 nm and the other at 880 nm. A light detector harnesses the reflected waves. The pulse oximeter probe and signal processing algorithms have been developed and manufactured exclusively for the AMON project by SPO Medical Equipment Ltd, Israel[6] based on a specification by MDirect.

B. ECG Sensor

To obtain an ECG, the patient must be physically connected to a front-end amplifier with special bioelectrodes that convert ionic current flow of the body to the electron flow of the metallic wire. Silver-coated chest suction electrodes or adhesive silver/silver-chloride electrodes with chemical paste or gel can be used. The first prototype of AMON used silver/silver-chloride electrodes without paste or gel. During the first prototype testing, the electrodes oxidized after two to three months and the input resistance raised to a level where no ECG signal could be measured. To eliminate oxidation, the second prototype used gold electrodes. The contact resistance is slightly higher, but a reasonable signal quality can be obtained (Fig. 4).

1) Electrode Configuration: All electrodes are mounted in one wrist-worn device. These are placed as follows (Fig. 3): Left arm (LA) electrode is inside the cuff, right arm (RA) electrode is on top; during a measurement, the patient must touch the RA with his left hand. The right leg (RL) electrode is placed on top pointing to the wearer; during measurement, this electrode must be in contact with the abdomen. In order to reduce common mode interference, a right leg drive circuit has been chosen [14] with gain set to 39 [15].

A high pass [cutoff 0.05 Hz] and a low pass [cutoff 100 Hz] filter is integrated in the amplifier stages. The signals are then digitized at 500 Hz sampling frequency.

2) Algorithm: The aim of the algorithm is to detect and measure a number of medical parameters from the ECG waveform, in particular, QRS complex width, RR distance, and QT interval. A further desirable parameter, PR interval, was left out for this work due to the nontriviality of P wave detection [16].

In keeping with the near real-time requirements and low processing power, a necessary requirement is that the algorithm is simple but accurate. The approach taken is based on a simplification of the QRS detection scheme of Pan and Tompkins [17]. This processes the sampled data as follows:

1) Differentiation—obtain information about signal slope.
2) Squaring the derivative—intensify frequency response curve of derivative.
3) Integrate over moving window—obtain information about slope and width of QRS complex; also filters out some unwanted spikes.

For QRS detection, a threshold set is computed during an initial learning stage (lasting 8 s): the upper threshold is calculated from 0.4 times the average maximum on the integrated signal; from this, a lower threshold is calculated by another factor of 0.4. During the detection process, the current integrated moving window value is compared with the upper threshold. If this threshold is exceeded, an R wave onset is assumed; QRS is confirmed by scanning backward (up to 100 ms) for a dip below the lower threshold. These threshold values are continually adjusted with each new QRS so as to compensate for variations in ECG baseline.

R wave is detected simply by searching for a peak in the raw signal following the detected QRS onset. Searching backward for the closest negative slope from R obtains the Q wave. Similarly, the S wave is found by searching a positive slope forward of R. The maximum slope forward of S (for about 100 ms) is denoted the T onset. An estimation of the T point is found simply by adding 80 ms to this.

The distances RR, QRS, and QT are stored for every discovered QRS wave. For an overall result—as displayed to the user—averages are taken over all the valid QRS. Heart rate is calculated directly from RR.

C. Blood Pressure

1) Hardware and Algorithm Principles: The blood pressure measurements employ the standard oscillation method [18]–[20]. The wrist and its vasculature are compressed by an encircling inflatable compression cuff. The principle of the oscillometric method is a measurement of the amplitude of pressure change in the cuff as the cuff is inflated to about 30 mmHg above systolic pressure and then deflated at a rate of 2–4 mmHg/s. The oscillation signal varies from person

[6]SPO Medical Equipment Ltd. [Online]. Available: http://www.spomedical.com/

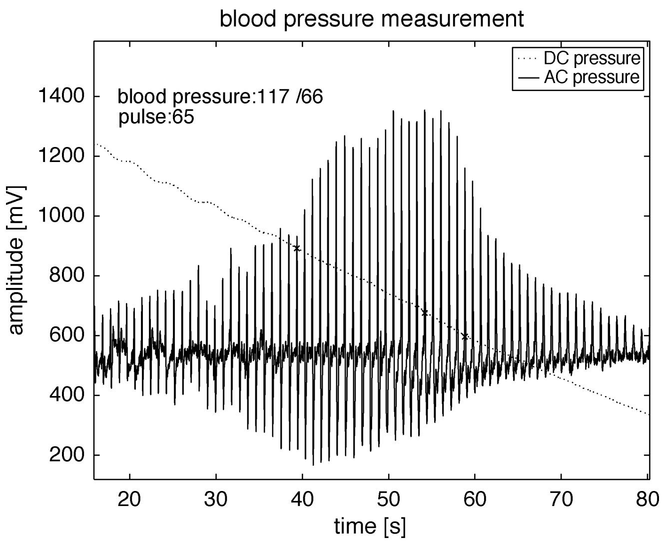

Fig. 5. AMON blood pressure sample measurement: Standard oscillometric method is applied to calculate systolic and diastolic pressure; pulse measurement is done by peak detection in the ac signal.

to person, in general, it varies from less than 1 mmHg to 4–6 mmHg (Fig. 5). For prototyping the cuff, pump and valve are taken from an OMRON device (model R5-I). Inflation and deflation rates are controlled by varying the power to the pump and valve using pulsewidth-modulated signals.

When measuring blood pressure at the wrist, it is important that the wrist with the cuff is positioned at the same level as the heart. Best results are obtained when the left arm (with the device) is positioned at, but not holding, the shoulder.

The pressure signal is split into high frequency (0.03–30 Hz) and low frequency parts (0–10 Hz).

2) Implementation:

a) Pressure: The blood pressure algorithm detects peaks and finds the maximum of the peaks in the high frequency part of the signal. To reduce noise, a small moving average window and later a curve approximation for the maximum region is applied. After removing the offset of 540 mV in the high frequency signal, the standard algorithm of the oscillation method is applied.

b) Pulse: The algorithm for pulse calculation is based on peak detection. The time difference between two peaks is averaged between systolic and diastolic pressure; this is then converted to peaks per minute.

D. Acceleration Sensor

Acceleration sensors provide information on the activities of the wearer. Three uses of this information are made: First, the pulse limits are set according to the activity level—e.g., walking, running, or resting [21]. Second, a potentially dangerous fall could be detected [22], [23]. Finally, a total lack of movement, combined with recent temperature and physiological sensor readings, can be used to indicate one of three possible scenarios: device has been removed from wearer—a constant abnormal temperature and a complete lack of useful data from the sensors; wearer falls unconscious—a measurement was halted prematurely, earlier readings having indicated an emergency situation; rest or sleep—recent readings have not given reason to suspect the onset of an emergency situation.

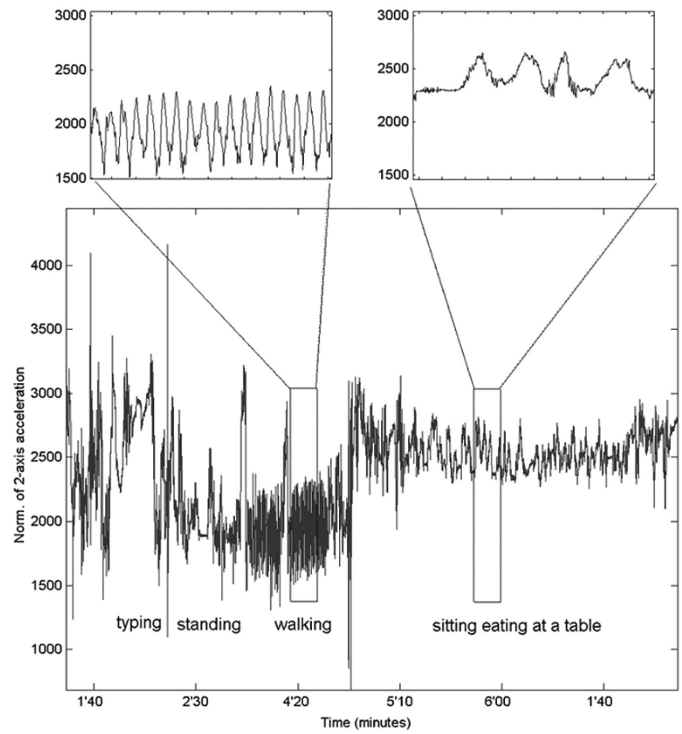

Fig. 6. Activity readings: normal two-axis acceleration data from the wrist during typical daily activities.

In the later cases, it is acknowledged that any decisions regarding the device and wearer's state must be made by trained personnel at the TMC. The degree of movement should, therefore, be presented at the TMC as another parameter to be monitored alongside the physiological readings.

1) Activity Detection: The AMON system requires only very simple activity analysis compared to other wearable activity detection applications, e.g., [24]. What we are interested in is the level of physical activity without being able to distinguish specific actions. The main problem that our analysis has to deal with is the fact that intensive arm motion by itself is by no means an indication of strenuous physical activity. Thus, for example eating, drinking, or just talking and gesticulating involves arm motions that are not particularly strenuous. Our analysis is based on the fact that strenuous activity is mostly associated with (fast) walking or running. This in turn has a characteristic periodic acceleration signature with the frequency indicating the walking speed (see Fig. 6). This periodic signature can be detected even if the arms do not follow the walking motion directly through swinging and are engaged in some other activity.

E. Temperature Sensor

The temperature measurement has been included in the device for experimental purpose mostly. The consortium has intended to study if a reliable correlation between the sensor reading at the wrist and the core body temperature could be established. Unfortunately, this has not succeeded and the sensor cannot be used for medical purposes. Hand temperature

TABLE I
L1 AND H1 REPRESENT DEVIANT ZONE, L2 AND H2 RISK ZONE, AND L3 AND H3 HIGH-RISK ZONE

vital sign	L3	L2	L1	Normal	H1	H2	H3
Systolic (mmHg)	50-59	60-79	80-99	100-130	131-160	161-200	201-300
Diastolic (mmHg)	40-44	45-49	50-59	60-85	86-90	91-110	111-140
SpO2 (%)	65-79	80-91	92-94	95-100			1001
Pulse (per minute)	40-44	45-49	50-59	60-100	101-120	121-180	181-250
QRS duration (s)	0.01-0.03			0.04-0.12			0.121-0.35

can vary depending on environment conditions and no fixed relationship with body temperature can be established [25]. The sensor is, therefore, used only for functional testing and together with the acceleration sensor for verification if the device is being worn.

F. High-Level Medical Algorithm

The AMON high-level medical algorithms integrate data from different sensors on a single device. To our knowledge, no such algorithms are in clinical use today at a home-care setup. All wrist medical algorithms are based on several sets of limits for vital signs. Based on comparison of these standard—or precustomized—limits, the measurement results are assigned to one of five zones—normal, deviant (abnormal values), risk, high risk, and error. The default medical ranges (see Table I) are set according to medical standard values, based on World Health Organization recommendations.[7]

The wrist device has two customizable sets of parameters, which are set by the health-care provider when handing the device over to the patient. The parameter values can be changed by the user's physician, the care provider, or in real time by the medical operator in the TMC via the cellular link.

The two sets represent a *nonaerobic state* and an *aerobic state* corresponding to the level of user activity. The parameters are set accordingly to age, gender, fitness, and medical history. The selection of the active set is performed by user command or automatically by the wrist device when activity is detected.

The clinical algorithm follows five steps, as follows:

- First Step: Compare measurement results to a range of values, and assign a risk zone accordingly.
- Second Step: Check the zone limits based on the average value derived from the last five results. Check erroneous measurements due to a possible problem with the sensors.
- Third Step: When previous steps indicate a risk or high-risk zone, determine if and what new measurement set is required.
- Fourth Step: Calculate pulse based on two or three different measurements (SpO_2, blood pressure, and ECG). Each measurement is weighted according to its reliability.
- Fifth Step: Pattern recognition of the medical data for clinical diagnosis.

On each step, a result is displayed and, if appropriate, sent to the TMC for further processing.

[7]World Health Organization. [Oline]. Available: http://www.who.int/

IV. SUBSYSTEM IMPLEMENTATION

A. Wrist Device

Fig. 7 shows the five functional blocks of the wrist device: power supply, sensors, man–machine interface (MMI), analog unit, digital processing unit, and communication subsystem. The wrist device prototype weighs 286 g, the estimated run time is two days (see Table II) and includes 4 MB of flash and 136 kB on Chip SRAM for program and data storage.

1) Low-Power System Design: Battery life is one of the major design constrains in mobile health-care systems. The system must be constantly operational without the need to frequently change or recharge batteries. User expectation from widespread use of cell phones is that a device should run for at least a couple of days.

Several techniques are known from literature to reduce power consumption [26] such as dynamic voltage scaling (DVS) [27] and dynamic power management; this includes putting unused modules or components in sleep mode and clustering of communication.

Each functional module of AMON has different ways of reducing power consumption. The following paragraphs describe the applied low-power techniques.

a) Power supply: Several modules run at different voltages: digital parts 3 V, central processing unit (CPU) core voltage 1.8–3.0 V, analog module 5 V, communication subsystem, pump, and valve at battery voltage (3.7 V).

Five volts is generated by a step-up converter supplying the analog unit, the efficiency is 85% (1–50 mA output current). The efficiency drops to 10% or less if the power consumption is below 0.1 mA. The step-up converter is only on during blood pressure, temperature, ECG, and battery voltage readings. The influence of the ripple introduced by the switched converter is reduced by filtering and amplifier configuration.

Step-down regulators have higher efficiency than linear. The variable voltage (1.8–3.3 V) is regulated by a step-down converter at an efficiency of 93% (1–200 mA). A digital potentiometer in the feedback path adjusts the output voltage for DVS. The digital 3-V supply is obtained in a similar way.

b) Sensors: Sensors were selected with low power considerations in mind, where feasible passive sensors were chosen (temperature, ECG electrodes, pressure).

The pulse oximeter was designed by SPO Medical Equipment Ltd. for low power; the datasheet reports 3.3 mW during measurement. Unfortunately, under test this is nearer 10 mA (an issue currently being resolved by the company concerned).

c) Display: The power consumption of the display is 70 μA, backlight about 50 mA. For most of the time, the backlight will be off as it is only activated when the user presses a button.

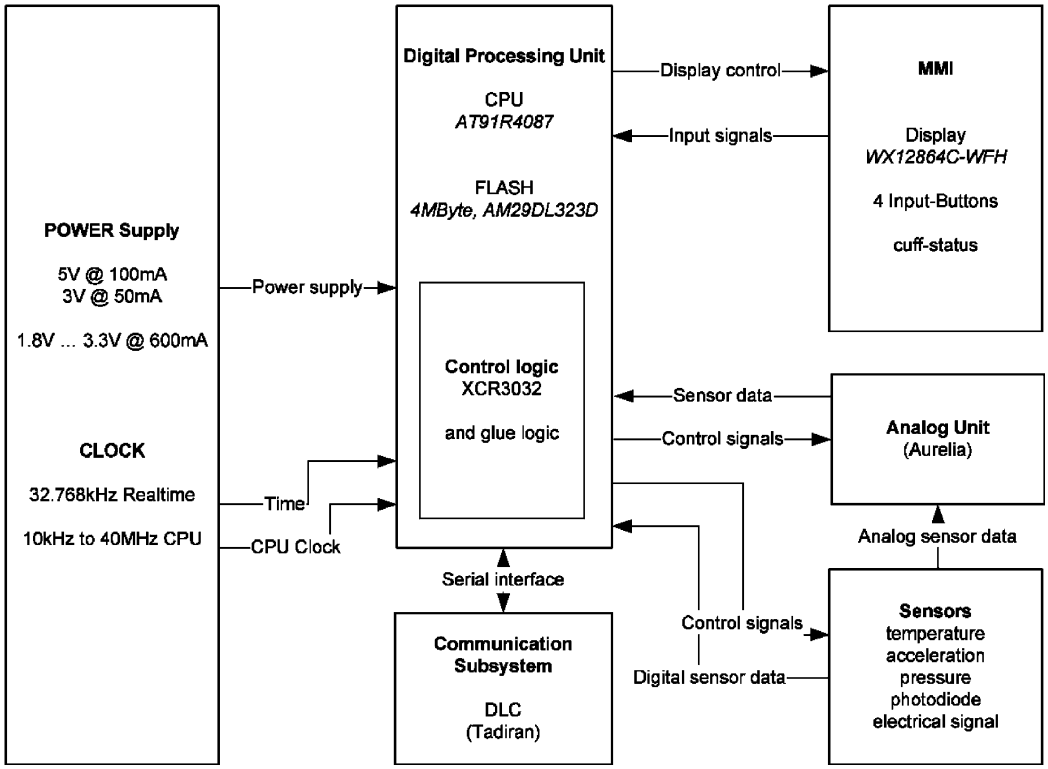

Fig. 7. Block diagram of the AMON wearable health monitoring device. Functional blocks: power supply, sensors, MMI, analog unit, digital processing unit, and communication subsystem (DLW).

TABLE II
POWER BUDGET OF THE WRIST DEVICE. DUTY CYCLES ARE BASED ON A TYPICAL DAY. BATTERY IS A 1.25 AH LiION; CURRENT IS MEASURED FROM PROTOTYPES

function	current	voltage	duty cycle	current eff.
GSM	3.5mA to 2.3A	battery	2.0 %	12.5mA
Inflating	220mA	battery	0.3%	0.7mA
Deflating	90mA	battery	1.0%	0.9mA
Analog Unit	40mA	5V	4.5 %	1.8mA
Digital Unit	9mA	1.8 to 3V	50%	4.5mA
SPO	10mA	3V	50%	5.0mA
Total				25.4mA

d) Analog unit: Special care for low-power design was put in the analog processing unit. Originally it was foreseen to use a custom application specific integrated circuit (ASIC), which would have an expected subsystem consumption of less then 50 mW. Using aggressive low-power design technique, a power consumption below 1 mW is possible [28]. Unfortunately, the ASIC was not fully working by the project end; instead a discrete version, developed in parallel, was used for the prototypes. The consumption, thus, nears 120 mW [Section IV-A1-g].

e) Digital processing unit: For the most part, the wrist device shows time, pulse, and oxygen saturation (SpO_2), which is measured every 2 min for 30 s.

Although the SpO_2 measurement is taken frequently, most of the calculation is performed using its own ASIC. The central CPU has no computation tasks and needs only to handle the communication protocol, thus, the load is low.

The AT91R40807 CPU allows a core voltage down to 1.8 V (at maximum 18 MHz), maximum operation frequency is 40 MHz (3-V core Voltage). According to the datasheet, power consumption can be reduced from 135 (at 40 MHz, 3.0 V) to 22 mW (18 MHz, 1.8 V). The clock frequency can be reduced further; this reduces idle power consumption.

The computation load varies from 30 MIPS during ECG and blood pressure measurements to a few commands every second for updating time or starting an SPO measurement. The use of DVS would help to tune the computation capability according to these needs [29]. However, at time of writing, this has not yet been implemented for this project.

f) Communication subsystem: The prototype uses a Siemens TC35 Cellular Engine. The subsystem is in sleep mode most of the time, still connected to the GSM network, and power consumption is 3 mA. During data transmission/call, the current can go up to 1.8-A peak, but will average at 300 mA. In normal use, the link will be open for 10 min per day, to transmit 500 kB of data.

g) Power measurements: Table II gives an overview of the system power consumption. GSM, SPO, and the digital processing unit are the highest power consumers. The digital processing unit was measured at 3.0 V and 40 MHz.

Energy-wise communication via wireless is expensive. More run time can be gained if data transmission is carried out when the network quality is high, thereby requiring less signal power.

SpO_2 is measured for 30 s every 2 min. Our test showed that the sensor needs about 20 s to give stable results, thus, it has a duty cycle of about 50%.

The analog part is used during temperature, blood pressure, and ECG measurement and is turned OFF most of the time (duty cycle of 4.5%). The replacement of the discrete analog board with an ASIC will reduce the power consumption at least by a factor of four.

A blood pressure measurement takes about 20 s to inflate and 80 s to deflate the cuff. A duty cycle of 0.3% for inflating and 1.0% for deflating represents ten measurements per day. Further improvements in the blood pressure algorithm can reduce the time for measurement, e.g., reduce end pressure of inflating or stop the measurements after diastolic pressure is passed.

B. Communication

The main task of the AMON communication system is to transmit reliable sensitive medical information through a secured channel from the AMON wrist device to the TMC and to handle requests/instructions from the center to the user.

To implement the above requirements, the communication protocol has been designed to support three types of communication channels.

1) SMS using the service provided by mobile phone network operators throughout Europe. This is used for messages with a small number of values, such as with the blood pressure results.
2) Virtual circuit switched communication channel established between the wrist device and the TMC through a mobile phone link. This is used for long messages such as a raw ECG data. It is essential in an emergency situation when a real-time link is needed between the medical personnel and the patient's device.
3) An Internet-based channel such as a file transfer protocol connection or custom TCP/IP-Stack. This has been foreseen to reduce the number of direct lines needed at the center and provide more efficient international communication in future applications.

The communication protocol has been designed in such a way that all three channel types rely on the same message structure: header, message body, and tail. The header includes information such as source and destination of the message and the type of content. The body contains the results of the medical measurements (processed results or raw data), and the tail enables error correction capabilities.

The communication system implements the requirements of European legislations regarding data privacy [30]. The legislation determines that respect for the patient's privacy should be guaranteed at all times during the processing and transmission of medical data. It is implemented by first removing any identity of the user from the data and then performing encryption and authentication (as part of the inherent GSM/GPRS protocol).

The communication system consists of a controller that is responsible for all the above activities and of a cellular engine (GSM). From the cellular network point of view, the AMON device acts in the same way as a regular cellular phone.

Since the mid-1990s, research groups have been working on methods to calculate the position of a mobile device connected to a GSM network. As long as the serving cell is known, location accuracy of several hundred meters in urban regions can be obtained. Other methods to enhance the position quality are described in [31] and [32]. This will help to locate the wearer of AMON and to send an ambulance if needed.

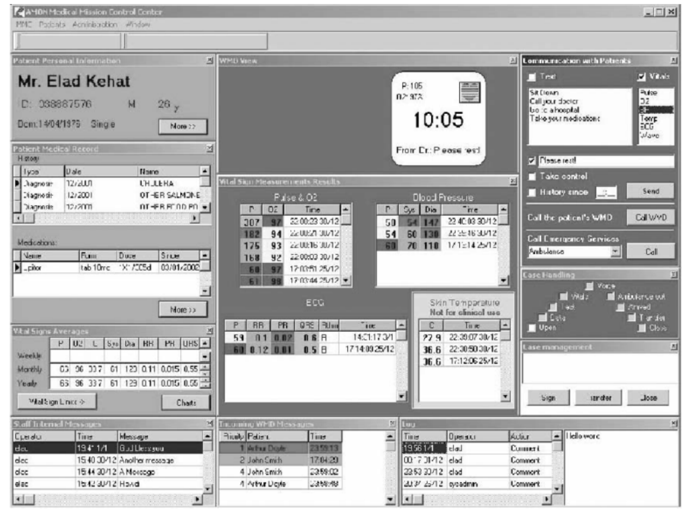

Fig. 8. TMC screen: Personal information, medical records, medications, internal messages, vital sign measurements include archived data and communication panel.

C. TMC

The TMC is based on a JAVA server platform running on a Windows PC with a GSM data link. The TMC facilitates, tracks, monitors, and reports the patient condition. Medical data transmitted from the wrist-worn device is analyzed by specialized software, designed by MDirect, on the TMC server. The server software compares the data to previous medical results in the archive and displays them in order of priority, issuing auditory alerts to the physician if necessary (Fig. 8). The physician has the ability to view the patient medical record and profile as logged on the server. The medical records summarize the medical history including diagnosis, medications, and personal information such as ways to contact the patient. The purpose of this is to provide a mechanism for the consolidation of all information associated with the care and administration of a patient in a variety of environments including their home.

Within the TMC, the operational staff may triage from remote and analyze the data received from the wrist monitoring device. The support by the online TMC staff is based on expert knowledge and trend analysis of previous recorded data. For each sensor and individual parameter, an algorithm analyzes the data and examines whether the parameters are within the normal medical standard limits or within predetermined values. This provides initial diagnostic, evaluation, and support services for the clinicians and the user of the system. High-level algorithms analyze the multiparameter data which arrives, including the medical history, and alerts the medical staff accordingly.

The workstation enables the following:

- remote monitoring of the AMON device;
- support and management functions such as patient diagnostic processing, clinical records review, exception condition processing, and reporting;
- direct contact with the patient;
- access to the historic medical file of the patient.

The medical algorithm system monitors the frequency of data input from users, screens which vital signs are more often out of range from the normal values, and alerts if the values start to shift to the edge of their range over time. The staff undertake extensive accredited training for managing such a system including the legal ramifications of their role. While covered by best practice and current knowledge defence in cases of litigation, the final arbiter of care decisions is the clinician treating/monitoring the patient.

Only qualified operational staff (nurses, qualified physiology technicians and physicians), each with individual user name and password, have access to the medical data. All medical data is secured according to the data-protection ACT 1998, as enforced across Europe from March 1, 2000. When a medical record is open, there is a digital stamp of time, date, and authorized access name. The database itself is secured on a dedicated server.

The TMC acts as a filter and monitoring service for active management of patients using the system. It is envisaged that this system will improve efficiency and effectiveness of home health care. The authors are aware that more advanced ways to present and preprocess the data coming in from the wrist device would enhance this effect. However, since the data is used for critical decisions, any automatic preprocessing must be carefully considered. Since the focus of the project was on the mobile device, such development has been postponed for further research.

TABLE III
MEASURED PARAMETER RANGE AND ASSIGNED PATIENT ZONES DURING THE MEDICAL VALIDATION

parameter	measurement range	patient zones (Table I)
Systolic (mmHg)	104 to 150	29 Norm. and 4 H1
Diastolic (mmHg)	70 to 99	26 Norm. and 7 H1
SpO2 (%)	95 to 100	33 Norm.
Pulse (bpm)	55 to 102	31 Norm., 1 H1 and 1 L1
QRS (s)	0.06 to 0.18	32 Norm. and 1 H3

TABLE IV
GRADING OF MEDICAL VALIDATION. FOLLOWING AAMI (ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION) CRITERIA

Blood pressure: 132 measurements, 87%(116) produced results			
	< 5 mmHG	< 10 mmHG	< 15 mmHG
Systolic	54% (62)	77% (89)	85% (99)
Diastolic	43% (50)	65% (76)	85% (99)
	< 5 bpm	< 10 bpm	< 15 bpm
Pulse	39% (45)	46% (53)	53% (62)
SpO2: 198 measurements, 68%(135) produced results			
	< 5%		
O2 saturation	78% (105)		
	< 5 bpm	< 10 bpm	< 15 bpm
Pulse	64% (86)	83% (112)	89% (120)
ECG: 66 measurements, 84%(55) produced results			
	< 5 bpm	< 10 bpm	< 15 bpm
Heart rate	50% (27)	71% (39)	76% (42)

V. MEDICAL VALIDATION

The goal of the medical trial is to confirm the possibility of reliably using several sensors in the same wrist-type device—without compromising on medical accuracy, as compared to standard measurement approaches. Additionally, in order to gain some feedback on user perceptions and wearability of the device, each subject was given a questionnaire to fill out.

The following parameters have been validated:

- Pulse oximeter: blood saturation in oxygen (SpO_2) and pulse.
- Wrist-type blood pressure monitor: systolic, diastolic, and pulse.
- Three electrodes recording cardiac activity in one lead configuration: QT, QRS, and heart rate (RR interval).

The study was conducted on 33 healthy volunteers. The volunteers have been recruited in the SAMU 92 and the Paris Ouest Medical School. Any volunteering healthy subject aged from 18 to 79, with no cardiovascular past history, nor any pulmonary disease could participate. Table III shows the measured range of the vital parameters.

The device was tested for a period of 70 min on each subject. The blood pressure measurement is compared to that manually measured by two trained investigators. As regards the other measurements, the AMON device is compared to other devices present on the market and fulfilling the CE norms. The SpO_2 measurement is compared to Datex cardiocap II and Nellcor NPB 40. The pulse measurement obtained by the wrist-type blood pressure monitor and the pulse oximeter is compared to the heart rate measured by the cardioscope of reference, Physiocontrol Lifepack 8. The recording of the cardiac activity is compared to the printed recording of the same period by the reference cardioscope. The comparison elements are the QT, the length of the QRS and the heart rate (RR interval). The statistical analysis is carried out separately for each sensor. The statistical method used is the Bland–Altman method [33].

A. Results

The wrist device declares that a measurement is erroneous in two situations: the wave form could not be detected, e.g., too much noise; and when the calculated parameter lies outside the valid risk zones in Table I. The assumption of the later situation is that values produced outside a valid zone are regarded as highly improbable—in particular, during the medical trials, it is known that all subjects could not possibly exhibit readings outside their range. Of course in a field situation, the values would be reported back to the TMC regardless, allowing trained staff to make the decision as to whether the device is broken or something is seriously wrong with the patient.

In calculating the Medical Validation results, such erroneous results were excluded from consideration. These results are presented in Table IV; below we give some further comments to these results together with some findings from the questionnaire.

1) Measurement Results: A close investigation of the raw blood pressure data showed a design flaw in the pulse algorithm; after the correction, 85% had a difference of less then five beats.

The deviation of the oxygen saturation measurement is far from the expected results. These results are insufficient for this system to be used with confidence in a clinical environment. The quality of the pulse measurement from the SpO_2 sensor is, however, good.

Regarding the ECG, although heart rate results could be obtained, there is no concordance in the QRS and QT results. These poor results were found to be due to high levels of mesurement noise. With such noise on the signal, there is no possibility of successful calculations using the on-device algorithms.

2) Remarks From Questionnaire: AMON was found comfortable by 70%; 10%—three female subjects with small wrist diameter—replied that the device was painful. The pain occurred when the blood pressure was taken.

All the subjects replied that the fact of carrying a device such as AMON would give them a feeling of security if they were suffering pathology at risk of acute complication. This sensation of security would allow them to resume their social activity and to go out. No subject has emitted a doubt about the respect of the confidentiality of the medical information for the patients being monitored by AMON. In no case, the confidentiality issue would prevent them from using a device of telemonitoring with transmission of the data.

The two investigating physicians and five nurses stated that a patient presenting a chronic disease, and more precisely a cardiovascular disease, could resume a somewhat autonomous life by carrying the device. However, they also stated that the design needs improvements and that the duration of measurements is too long. Additionally, it is believed that user training may be required for some of the measurements, e.g., blood pressure.

B. Conclusion

1) Measurement Results: Concerning blood pressure, the systolic pressure results are good and may lead in a future development to a final product that operates on a daily clinical basis. Diastolic measurements need to be improved and revalidated afterwards.

Measurement of blood saturation using the reflectance sensor does not provide reliable results. Nevertheless, the pulse measure using the oxygen blood saturation sensor provides good results. Detection of the pulse is a prerequisite for the measurement of blood saturation. The good measures of pulse are an encouraging aspect of this technique, which will need further development. Moreover, it is the first time the sensor is used in this configuration and in such an environment.

ECG provides poor or no results. Calculation of reliable heart rate and length of the QRS wave was not made possible. Noise was a problem for all measurements. Improvements hardware and algorithm-wise are foreseen and should improve the measurements significantly.

The results are close to what we expected but the device needs some improvements. What can be stated is that the use of several sensors in the same device is possible.

2) Remarks From Questionnaire: For almost all the users (both subjects and investigators), the device has been positively rated. The answers stress the technological breakthrough and the amelioration for the patient. It can be stated from these results that there is a demand for this kind of device both from the patient's and health-care provider's point of view.

An important point in all of the subjects' responses is that such a technology-rich device must be totally reliable.

A second set of remarks underlines the importance of the visual and comfort aspects of the device. It is required that the functioning of the device does not hamper the daily life of the patient. If the device increases the autonomy of the patient, it must still have an aspect compatible with a daily social life. Likewise, this ties in with importance of comfort, as stressed earlier. The forecast by users of the device are very encouraging.

VI. Conclusion

We have developed a wearable medical monitoring and alert system aimed at people at risk from heart and respiratory disease. The system combines multiparameter measurement of vital signs, online analysis and emergency detection, activity analysis, and cellular link to a TMC in an unobtrusive wrist-worn device. A prototype of both the wrist device and the medical center software has been implemented. Medical trials were performed on 33 patients. While first prototypes had problems with achieving the required medical accuracy on all the measurement, the tests have provided a clear indication of the feasibility of the concepts and validity of the solutions adapted by the project.

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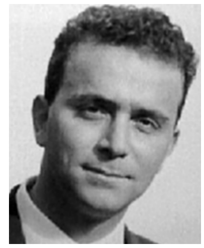

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