Wearable, multimodal, vitals acquisition unit for intelligent field triage

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In this Letter, the authors describe the characterisation design and development of the authors' wearable, multimodal vitals acquisition unit for intelligent field triage. The unit is able to record the standard electrocardiogram, blood oxygen and body temperature parameters and also has the unique capability to record up to eight custom designed acoustic streams for heart and lung sound auscultation. These acquisition channels are highly synchronised to fully maintain the time correlation of the signals. The unit is a key component enabling systematic and intelligent field triage to continuously acquire vital patient information. With the realised unit a novel data-set with highly synchronised vital signs was recorded. The new data-set may be used for algorithm design in vital sign analysis or decision making. The monitoring unit is the only known body worn system that records standard emergency parameters plus eight multi-channel auscultatory streams and stores the recordings and wirelessly transmits them to mobile response teams.

1. Introduction: Natural or man-made disasters that result in a large number of human casualties always pose difficult challenges. Since 1900 the probability of occurrence as well as the degree of severity of mass causality incidents has increased, but since 1985 have shown a more severe trend [1]. 'Especially climate related disasters affected 217 million people each year since 1990' [2]. Summarised data over the past four years on complex, natural and technical disasters worldwide draws an even more dramatic picture with 400.000 plus victims and 676 million people affected. The International Disaster Database estimates the total damage to have cost more than USD 790 billion [3]. The main challenge in these situations is to gain high quality information in order to develop a methodical approach for the assignment of the limited resources. Since most disasters occur spontaneously, people are often unprepared when they happen.

Consequently, today's emergency management systems will have to adapt to improve their concepts, using all experience available and making use of the newest technology. When a disaster occurs first responders usually work according to predefined procedures. In an overwhelming crisis situation with lacking medical resources they follow a dedicated concept: triage. It is a stratification procedure to locate, assess and treat all subjects and finally prepare them for transportation, using prioritisation [4]. Modern concepts from other application areas such as bringing healthcare services to the patient [5], or medical care in rural areas [6], as well as new technologies, such as wireless transmission, embedded systems, powerful algorithms or new body worn multisensory systems for human vital sign acquisition [7] may be of great help.

In a former publication [8], we presented the system architecture in detail, emphasising the application and design. The objective of this project is to provide an innovative system to help first responders gain real-time human vital information and thus optimise resource usage and assignment. In this Letter, we focus on the device characterisation and experiments to prove functionality. The objective of this milestone is to characterise and prove proper functioning of all modules and subsystems, and to create a new and unique data-set with highly synchronised human vital signs.

2. Related work: This system has been developed to acquire human vital signs including multi-channel auscultation of heart and lungs in an emergency setting to assist first responders in the triage process. From a technological perspective, the proposed system is a vital signs monitor and thus comparable with others by careful inspection of the system's acquisition modalities. An

equivalent system or device would incorporate at least a standard set of vital signs sensors (electrocardiogram (ECG), blood oxygen, blood pressure, electroencephalogram (EEG) etc.) plus multi-channel auscultation.

As part of a review of body-worn health monitoring systems, including the survey of Pantelopoulos and Bourbakis [7, 9–13], 24 commercial and academic systems were analysed. This review indicated that no system for use in an emergency setting involved highly synchronised multi-channel auscultation.

Only one PC-based prototype system published by Bravo-Zanoguera *et al.* [12] presented a three-channel PCG with synchronised ECG for educational purposes. 'This tool presents a visualisation interface that assists teaching of the cardiac cycle.' The system is capable of displaying PCGs and ECG concurrently to facilitate the understanding of the cardiac cycle.

None of the described work involves wearable human vital signs acquisition including multi-channel auscultation for an emergency setting, although PCGs and related data processing algorithms experience an increasing interest in research, especially in the field of algorithms. The research indicates that, although stethoscopes are one of the oldest and most widely used tools in the medical profession, none of the analysed systems are capable of collecting and transmitting such a broad synchronised data-set. Research results also show a wide variety of strategies, systems and methods, but have proven that there is no 'one-fits-all' approach. Often conflicting design parameters such as sensor count versus usability or data rate in wireless communication versus power consumption require a careful trade-off with respect to the intended use.

Additional related work [9–11] emphasising the application point of view was discussed in a former publication [8].

The Mobile Client Unit (MCU) presented here is a body worn health monitor with the following unique features: (i) multi-channel auscultation with up to eight custom designed acoustic channels and in addition, (ii) ECG, pulse oximeter, and temperature sensors; (iii) highly synchronised data acquisition; (iv) generous computational performance for onboard parallel processing; (v) high bandwidth and extended range Wi-Fi interface for high volume data transmission; (vi) large onboard storage (up to 24 GB) for recording to allow offline processing; and (vii) a three tier architecture that differs from the common approach described in [9, 14].

3. System: The wearable, multimodal, vitals acquisition unit for intelligent field triage is organised in a three-tier architecture as shown in Fig. 1.

Fig. 1 Three tier architecture. Multiple MCUs connect with mobile nodes to create clusters. Latter communicate with a central node which provides medical and organisation information for transport and hospitalisation

Layer 1 represents the emergency site. The first contact between the medical rescue team and subjects involve both the initial assessment the same way as in common triage procedures and the application of body-worn MCUs for continuous assessment. During the initial assessment the medical rescue team tries to determine name, gender, age group, major injuries, to take a picture and store the location. This is a guided process with the aid of mobile nodes (smart phone with dedicated app). Thereafter the medical rescue team applies the MCU and associates it with the patient's data-set. The continuous assessment of the vital signs starts and involves acquisition of ECG, blood oxygen, auscultatory data and body temperature. Initial and continuous assessments combine with a comprehensive continuously updating physical reflection of information supporting the triage process and enabling advanced resource allocation at the emergency site.

Layer 2 forms scalable clusters continuously collecting, analysing, storing and displaying vital signs from the MCUs. The mobile nodes function as multi-subject emergency parameter monitors and relay data towards layer 3. It is intended that automated analysis highlights important information and triggers necessary alarms, e.g. subjects with deteriorating physical condition, to allow the rescue team to pay attention to life saving medical intervention.

Layer 3 represents transportation and hospitalisation with access to local internet to read medical and organisational information from the central node in real-time. Thus, every institution can perform individual preparation for every incoming subject before arrival.

Data path: the MCU is connected to tethered sensors to record the vital signs. The data is then preprocessed and sent to the next mobile node using the included Wi-Fi interface. The mobile node further processes, stores and transmits all data-sets to a central node (server) using standard internet access or mobile phone networks. The location independent server, herein referred to as central node, provides all data to the next in line institutions, such as ambulances or hospitals.

3.1. Acquisition modalities: To identify most suitable vital parameters to reflect the subjects' physical condition, various mobile emergency monitors and emergency case protocols were inspected [15]. Most common are (i) ECG, (ii) pulse oximetry, (iii) blood pressure (non-invasive blood pressure (NIBP) with arm cuff) and body temperature. For this project standard acquisition

modalities such as ECG, blood oxygen and body temperature provide a solid and well known data basis. Blood pressure shall be added at a later stage, because cNIBP is an interesting non-invasive concept that does not rely on an arm cuff [16]. cNIBP uses just ECG, pulse oxymetric output and the timing correlation. This monitor keeps the timing correlation of all signals, thus a complete subsystem can be replaced by an algorithm. Heart and lung sounds contain additional information that would round out the view of the physical condition of the subjects. Thus, multiple acoustic streams from heart and lungs add a completely new acquisition domain and allow identification of auscultation based diagnoses such as heart insufficiency, heart valve rupture, pneumothorax, blocked airway or punctured lung, to name just some examples.

Upcoming experiments may show that additional human vital signs such as EEG, body movement, or organisational aspects such as location, triage class and so on, are mandatory to acquire

Fig. 2 MCU with: (1) baseboard; (2) ECG daughterboard; (3) ChipOx® daughterboard; (4) LiPo battery; (5) high bandwidth parallel raw data output or debug interface; (6) up to 24 GB MicroSD® card and slot; (7) USB 2.0 power and data port; (8) six stethoscope leads for heart and lung sound auscultation (two channels record ambient noise – not yet used); (9) ECG patient lead connector; (10) Wi-Fi® connector (muRata SN8020 daughterboard not shown here); (11) ChipOx® finger sensor; (12) stethoscope leads with embedded microphones; (13) ECG patient leads

Fig. 3 Block diagram for custom designed MCU hardware depicting modularisation and eight channel acoustic front-end

or store. For maximum flexibility the system provides generic hardware interfaces for various daughter boards that allow further integration without changes in existing hardware.

3.2. MCU – hardware: The MCU hardware consists of a 90 mm diameter round baseboard carrying the field programmable gate array (FPGA) and periphery, power, storage ECG and pulse oximeter daughterboards, and a multitude of connectors as illustrated in Fig. 2. Due to the round design the system can be comfortably worn on the chest with a strap around the neck. The Wi-Fi® daughterboard is located in the case to minimise electromagnetic irradiation.

ECG and pulse oximeter patient leads, the temperature sensor and all custom designed electrical stethoscope leads have dedicated sockets and connectors. This allows users to easily adapt to experiments that use a subset of the available acquisition modalities.

In Fig. 3, the block diagram shows the fundamental hardware architecture of the custom designed and developed baseboard. The implementation has a high degree of separation to maintain module independency. All modules have dedicated interfaces that reflect provided functions. Therefore, modules and daughterboards may be changed or even replaced with minor adaption in hardware. Whereas the baseboard with FPGA, periphery, power management, acoustic frontend, flash, microSD® and temperature sensor is a custom design, ECG, pulse oximetry and wireless communication interface are standard OEM modules. This approach emphasises the design effort on new system parts, such as multichannel auscultation, rather than reinventing existing technology, such as ECG, by also reducing design risk.

FPGA: The high performance CPU is a powerful Xilinx Spartan-6® XC6LX9 FPGA (CSG324 package, 200 GPIOs). The Spartan-6® was chosen to have a safety margin related to computational performance, transistor and pin count. Drawbacks are a marginally higher power consumption, larger footprint and complexity. The chosen architecture allows parallel real-time onboard processing especially for multi-stream sound analysis.

Analogue front end: All eight custom designed electronic stethoscopes have Knowles® SPM0408HE5H MEMS microphones. They contain a built in analogue amplifier and have a sensitivity of 22 dB at 1 kHz. The low power design reduces consumption to 200 µA per microphone, resulting in 1.6 mA for all eight channels. The very small form factor (4.7 × 3.7 mm) allows implementation directly into the stethoscope head with a

pluggable shielded connection to the baseboard. Each acoustic channel has a second stage low noise differential amplifier followed by filters and differential signal tracing to one of two Analogue Devices AD1974® ADCs. These chips have four parallel ADSs (not multiplexed) and are based on a multibit sigma-delta conversion principle to provide low noise in the lower frequency range.

External modules: The EMB3/6® by Corscience GmbH is a CE® certified 3/6-channel OEM ECG module designed for mobile use. It has a small form factor (25 × 40 mm) and low current consumption (<26 mW). [17] ChipOx® by Corscience GmbH is a CE® certified pulse oximeter also designed for mobile use. It is very small (31 × 14 mm), has a low power consumption (40–90 mW) and comes with a raw data output feature, what is especially useful in research [18].

The muRata SN8200 is a CE® certified Wi-Fi module supporting the 2.4 GHz IEEE 802.11 b/g/n standard. The small size (30 × 19 mm) and low power consumption (280 mA at 100% duty cycle) make it especially useful for this project [19].

3.3. MCU – embedded application: The embedded application follows a strictly modular architecture based on horizontal and vertical separation as shown in Fig. 4. This ensures flexibility during development and supports the application's stability.

The user logic, startup routine, configuration and information management are organised in the **top-level entity** and define the main device behaviour.

A second horizontal layer, the sub-level logic, contains generic and task-specific logic. It was introduced to outsource functions from top-level logic, thus to reduce the size and complexity of the top-level entity.

The driver layer groups functionality into stand-alone drivers. Each driver provides a dedicated and module-specific application interface to the sublevel logic layer with functions such as

- ECG switch on/off.
- Set default PulseOx configuration.
- Read FPGA configuration status.
- Start ECG acquisition.
- Write data block to microSD® card.

The drivers communicate according to the specifications given by the hardware. In general the drivers and I/O layer have a byte-wise data exchange.

Fig. 4 Block diagram for FPGA application programmed in very high speed integrated circuit hardware description language (VHDL) with a strictly modular approach

The I/O layer defines the electrical and physical specifications of the data connection, has hardware access and does not contain application logic. It implements low level protocols such as universal asynchronous receiver transmitter (UART) and serial peripheral interface (SPI).

The user constraints file maps the logic signals used in the embedded application to FPGA I/O pins, which are physically connected to corresponding tracks on the PCB. It further defines the signal characteristics so that special internal function signals such as clock lines are routed appropriately.

Using best practice design patterns simplified design and programming and reduced complexity, increasing reliability at the same time. Some functions, such as UART and SPI protocols were programmed as a generic entity and instantiated as often as necessary. This approach is an advantage of strict modularisation and greatly accelerates development.

Various Xilinx simulation tools and a custom designed 17 bit debug interface provided a solid base for verification. The proposed system described here has about 10 k lines of code and requires 38% of the resources available.

3.4. MATLAB® application: For design and characterisation tasks a MATLAB® based host application with extended General User Interface (GUI) was developed as shown in Fig. 5. It acts as a mobile node (architectural layer 2) in the first step and will be replaced by a tablet application, for example. It provides two

modes: *real-time mode* to acquire data from the MCU; and *offline mode* where stored data-sets can be loaded into the application. This allows quick preprogrammed off-line analysis, e.g. during running experiments.

3.4.1. General user interface: The GUI is divided into four parts to provide easy access to the most used functionality or convenience features.

- (1) *Recording:* the user can chose a time period, check settings and start a single or continuous recording. The MCU will immediately start acquiring as configured and will transmit the data.
- (2) *Single Mic analysis:* Some often used single-channel characterisation algorithms are embedded in the GUI to accelerate handling during experiments, e.g. to verify the setup.
- (3) *Multi Mic analysis:* Some often used multi-channel characterisation algorithms are available in a similar way.
- (4) *Log:* A text log was introduced to record the application status during runtime. This helps to prove the status or quickly identify problems.

3.4.2. Data transmission: The MCU continuously streams acquired and digitised sensor data to the MATLAB® application running on a laptop. The experiments described here were configured to transfer raw data with an approximate rate of 3.2 Mbit/s. This set-up uses

Fig. 5 Main GUI to assist the user in often used tasks. Additional functionality is available via MATLAB® command line

a muRata SN8020 Wi-Fi® daughterboard with a 1 Mbit/s UART-based bandwidth and thus is not capable of sending raw data. Therefore, a tethered 16 bit high bandwidth parallel output was implemented interfacing an Opal Kelly® XEM6002 board that supports data transfer at up to 11 Mbit/s and provides a driver to import the data directly to MATLAB®. The application receives, processes, analyses and displays the human vital data to the user.

In a next step, the ISO/IEEE 11073 communication model shall be considered. This complies with personal health device standards addressing the interoperability of personal health devices.

4. Device characterisation: The designed and developed MCU enables mobile and synchronised acquisition of ECG, blood oxygen, body temperature and multi-channel auscultation. ECG and pulse oximeter are CE certified OEM modules, thus correct acquisition is ensured. Therefore, data transmission, analysis and visualisation are emphasised during verification. The analogue front-end is a custom designed acoustic acquisition unit. The verification is very complex, but MDs with experience in auscultation can quickly give a qualitative feedback of the recordings, which shall be sufficient in a very first approach. The following chapters discuss experiments to prove the ECG module, pulse oximetry module and acoustic acquisition.

4.1. Electrocardiogram: To characterise the performance, recordings from the MCU were compared with a concurrently recorded ECG from a market device. The block diagram of the setup is illustrated in Fig. 6. Four custom made y-joint ECG patient leads were applied to the human thorax (left arm, right arm, left leg, and right leg) and signals from three subjects were recorded five times, at 20 s each recording.

To create a common time base reference on both independently working ECG systems, the subjects were asked to quickly touch a low voltage source at the beginning of each recording. This created a clearly visible marker, which was used to manually align the signals during post-processing. A comparison based on a visual inspection proved that both systems show similar behaviour. In the next step, the gain was eliminated using the MATLAB® function ‘detrend’ and both signals were normalised. Finally, the correlation was calculated using the MATLAB® function ‘corrcoef’. The average correlation is 0.94 which seems to be sufficient for reliable usage. Fig. 7 shows the post-processed curves used for visual inspection.

During normal operation the EMB3/6® consumed 25 mW, which corresponds to the value given in the datasheet.

4.2. PulseOx: To characterise the performance, the recordings from MCU were compared with concurrently recorded data from a standard Corscience OEM device. Both pulse oximeters were

applied with a finger sensor, one on the middle finger of each hand. Recordings were made on three subjects with five times 60 s each.

The modules provided SpO2, heart rate, plethysmogram, perfusion, and signal quality. The OEM device did not provide the option to export raw data streams for a comparison based on the same approach that is used by the ECGs. Instead, heart rate and blood oxygenation levels were logged at one second intervals and compared based on mean square error (MSE) calculated with the following equation

$$MSE = \frac{1}{n} \sum_{i=1}^n (x_i - \bar{x})^2 \quad (\text{Equation (1) mean square error [20]}) \quad (1)$$

The comparison resulted in a MSE of 0.08 for heart rate and 0.18 for blood oxygenation level, which seems to be sufficient for further usage.

During normal operation the ChipOx consumed 49 mW, which corresponds to the range given in the datasheet.

4.3. Heart sounds: Acoustic front end: Existing literature extensively describes the acoustic phenomena of heart and lungs. Both share a common frequency range [12, 21, 22]. Heart valve phenomena range from 300 to 400 Hz and the heart rate itself from 20 to 200 Hz. Normal and adventitious lung sounds contain the most recognisable energy between 200 and 600 Hz, such as pneumonia between 500 Hz and 2 kHz and pulmonary oedema and asthma bronchial between 500 and 800 Hz to mention just some examples. Today’s stethoscopes in general define three modes for examination: [23] (i) Bell mode 20 Hz–1 kHz emphasising 20 Hz–200 Hz; (ii) Diaphragm mode 20 Hz–2 kHz emphasising 100 Hz–500 Hz; (iii) Extended range mode 20 Hz–2 kHz emphasising 50–500 Hz. Considering all modes the lowest frequency is 20 Hz and the highest frequency is 2 kHz. With respect to the novel approach a generous margin was selected. Hardware cut-off frequencies are 0.15 Hz and 24 kHz, whereas the implemented embedded application has a band gap filter from 2 Hz to 5 kHz.

The eight analogue channels are identically configured and show similar behaviour in the frequency response, noise level, and intra-/inter-channel delay in the given frequency range. In this experiment, four acoustic channels were applied to four locations for auscultating corresponding heart valves (aortic valve, tricuspid valve, pulmonary valve, and mitral valve) [21]. The experiment was performed with one subject at rest and at an excited pulse rate of >100 heart beats per minute with the setup shown in Fig. 8. The setup did

Fig. 6 Block diagram of test setup for MCU ECG verification

Fig. 7 Synchronous recording of ECG with both Corscience development kit (blue) and MCU (red) after post-processing with MATLAB® 'detrend' function

Fig. 8 Block diagram of test setup for multichannel heart sound acquisition

Fig. 9 Block diagram of test setup for human vital data acquisition

not use any post-processing routines to optimise the acoustic streams.

Auscultating the mitral valve at location D produced the loudest results. A slight rise in sound intensity in all channels was experienced when the beats per minute were increased. The heart sounds S1 and S2 were visible and audible in all channels. Three MDs with significant experience were asked to listen to the playback and evaluate the acoustic quality. Their unanimous opinion was that the quality is comparable to standard mechanical stethoscopes and is sufficient for heart sound auscultation. A quantitative quality assessment, e.g. comparison with a Littmann® 3200 electronic stethoscope, is scheduled.

Inter-channel mismatches that may be attributed to different microphone batches, component variations and PCB locations of the components have not compromised the results of this qualitative approach, thus are negligible so far, but might have to be taken into account for more advanced processing tasks such as sound source

localisation. Timing on the other hand is very important and dedicated experiments were performed as described in the next chapter.

4.4. Synchronised acquisition: The MCU was designed to keep the time correlation of all acquired human vital signs. Thus, in the latest experiment, ECG, blood oxygen, and heart sounds were recorded at the same time. The experiment comprised recordings with ten subjects of three times 30 s at rest and three times 30 s at an excited heart rate above 100 heart beats per minute with the setup illustrated in Fig. 9.

The test setup showed a high degree of reliability and repeatability. A visual and acoustic inspection by three experienced MDs showed that all acquisition paths meet a suitable quality and that the signals are synchronised. A three second recording is shown in Fig. 10 with the following curves: (i) ECG, (ii) plethysmogram with pulse, SpO2 and finger sensor signal quality; and (iii) auscultation with channel 1. The red line indicates the R-to-S transition in

Fig. 10 Concurrent acquisition of vital signs. 1 – ECG; 2 – plethysmogram, pulse, SpO2 and signal quality of finger sensor; 3 – heart sound on channel 1

the ECG signal of the first heart cycle that correlates with the first heart sound S1 [21].

The expected heart sound patterns S1 and S2 are clearly visible. S1 is the most prominent artefact (following the red line) and S2 is the smaller artefact lying in between S1. The system proposed here keeps time synchronisation between the continuously recorded signals correlated as depicted by the red line and thus provides new analysis modalities. Recent development takes advantage of this feature and develops a performance optimised algorithm to extract S1.

4.5. Power consumption: The experimental setup used here has no power saving mechanisms of yet. In the normal use scenario – continuous recording of ECG, pulse oximeter, temperature, eight acoustic channels, and tethered raw data transmission – the MCU has a total power consumption of 494 mW. The system has a 3800 mAh at 3.8 V lithium polymer battery, thus the achievable single charge cycle at a given consumption of 130 mA at 3.8 V is slightly above 29 h.

Adding wireless transmission with ~50% duty-cycle and the local storage to buffer data total consumption is increased by ~110 mW and the achievable single charge cycle is +15 h.

5. Conclusion: The first step towards a Vitals Acquisition Unit for Intelligent Field Triage is accomplished. In this project, a human wearable multimodal emergency monitor unit to record ECG, blood oxygen, body temperature and up to eight acoustic streams for heart and lung sound auscultation was developed and tested. The system proposed here is the first of its kind with highly synchronised human vital signs recording capability plus

multi-channel auscultation. The new and unique data-set provides a new basis for algorithm design that may take advantage of the time correlation between different vital signs. It is a lightweight battery powered embedded system designed for mobile operation.

The system's architecture is designed for emergency scenes and is the only known platform that transmits other vital signs such as heart and lung sounds to central nodes that are independent from the acquisition location. The central node simulated with the MATLAB® application developed here is capable of receiving and visualising data in real time as well as providing data for offline analysis.

The proposed system with its unique data-set contributes in that it enables research on synchronously recorded human vital signs and provides a basis for new algorithms, for example such as: low performance S1 extraction, automated decision making, or automated diagnosing of pneumothorax, blocked airways or heart valve ruptures.

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