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Special Session Title:

Intelligent monitoring and diagnostics in lung diseases

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Theme:

- ○ 01. Biomedical Signal Processing
- ○ 02. Biomedical Imaging and Image Processing
- ○ 03. Micro/Nano-bioengineering; Cellular/Tissue Engineering &
- ○ 04. Computational Systems & Synthetic Biology; Multiscale modeling
- ● 05. Cardiovascular and Respiratory Systems Engineering
- ○ 06. Neural and Rehabilitation Engineering
- ○ 07. Biomedical Sensors and Wearable Systems
- ○ 08. Biorobotics and Biomechanics
- ○ 09. Therapeutic & Diagnostic Systems and Technologies
- ○ 10. Biomedical & Health Informatics
- ○ 11. Biomedical Engineering Education and Society
- ○ 12. Translational Engineering for Healthcare Innovation and Commercialization

Special Session Synopsis— Max 2000 Characters

Based on EUROSTAT, the diseases for the respiratory system, including conditions such as chronic obstructive pulmonary disease (COPD), pneumonia or asthma, are accountable for the 8.2% of all deaths in the European Union . In addition, the financial impact, translated into hospitalization days, medication costs, days spent in Intensive Care Units (ICUs), disability adjusted life years (DALYs), is also very high. Adding to these problems the last nine months brought the need to cope with the COVID-19 epidemic in the whole world. This virus predominantly affects lung function, and is extremely dangerous for elderly and people who have lung diseases substrate.
In the context of the above mentioned problems the EU funded WELMO project is developing new wearable sensors for bioimpedance estimation based on the EIT, as well as the recording of lung sounds, and thus the possibility of feature extraction in relation with lung diseases such as COPD or asthma. Additionally, a new system (CoCross) has been developed which is capable of recording lung and heart sounds, X-Rays and ultrasounds from COVID-19 patients in the ICU, thus adding much needed data and information that can be used for advanced digital diagnostics in lung diseases. Thus, the main objectives of this special session are:

- Presentation of new PoC and wearable sensor array based technologies
- Presentation of the health care models applicable in the precision medicine era
- Translation of user requirements in technical tools from sensors, systems, data analytics, user interfaces for achieving accurate lung digital diagnostics
- New large scale databases for setting benchmarks for HR-MD development
- New AI/DL/ML based analytics and feature extraction in

The WELMO project – Scope and objectives

Nikolaos Maglaveras, Aristotle University of Thessaloniki, GREECE

Abstract— **WELMO aims at developing, a new generation of wearable miniaturized sensors, integrated to a comfortable vest, enabling the effective and accurate monitoring of the lungs sounds and imaging from COPD and COVID-19 patients. A basic innovation is the development of a new technic for producing images of the lungs from Electrical Impedance Tomography (EIT) measurements enables y new microelectronics and ASIC technology, embedded in state-of-the-art wearable clothing.**

I. Introduction

According to EUROSTAT[1], **lung related diseases**, such us chronic obstructive pulmonary disease (COPD), pneumonia and asthma **are considered the main causes of death in the EU**. The same study revealed that there were almost 382 thousand deaths in the EU-28 resulting from respiratory diseases, equivalent to 7.7 % of all deaths, in 2014. Additionally, there is a high probability for people to develop lung related conditions that are non-lethal but still significantly degrading their quality of life (QoL). Additionally, the few (portable) electronic medical devices used in the clinical practice (e.g. digital stethoscopes or hand-held spirometers) enable only the monitoring of the lung function on a snapshot basis. Other medical devices, especially the radiological ones, are confined to specialized labs or hospital units. They are massive, expensive, not comfortable and difficult to operate, thus requiring specialized personnel. Several of them also rely on patients´ cooperation and compliance to guarantee proper examination results. Some of the radiological methods increase the radiation load. Other methods, like the non-invasive and radiation-free functional imaging method of EIT is presently used only in a small group of critically ill patients treated in intensive care units. The WELMO project will provide new wearable smart technology for seamleassly recording lung sounds and bioimpedance monitoring the lings and applying the technology in COPD and COVID-19 patients mainly.

II. Methods

The newly developed technology will be prototyped and demonstrated for **Electrical Impedance tomography (EIT[2]) and for lung sounds**. It will also **allow easy extension** to biopotentials (e.g., multi-channel ECG) or other type of bioimpedance (e.g., galvanic skin response or BIS, bioimpedance spectrography) as well as to any other signals, especially those sensed at distant points on the body (e.g., temperature map), **thereby providing a modular technology platform** opening the way to a multitude of form factors and products in a short time to market.

Overall the WELMO approach will rely on the following technology offerings: (i) low-cost and low-power innovative cooperative sensors integrated in a wearable vest through a single-wired connection, (ii) continuously monitoring of the lungs' condition through EIT and lung sound recordings, (iii) implementation of novel algorithms for processing the data collected and (iv) presentation of the processing and monitoring outcomes through a set of applications. The impact, acceptance and usability of the proposed solution will be validated in a realistic setup through the execution of excessive validation studies. Finally a business sustainability study will be carried out, aiming to the mid-term exploitation of the proposed solution. As the major goal of the WELMO project is the development of a high-usable, easy-to-wear, machine-washable wearable, enabling the efficient and accurate real-time (and continuous) monitoring of the lungs, the development of the WELMO electronics is placed at the core of this action. Exploiting innovative and existing technologies, is the key to the successful implementation of WELMO's electronic concepts. Overall, the objectives are:

Objective 1.1: To design, develop and produce a machine-washable, adjustable, and easy-to-wear, wearable:

Objective 1.2: To develop and produce miniaturized and low-power sensors: this includes sensors with size: diameter < 25mm, height < 3mm, and energy consumption less than 200 μA.

Objective 1.3: To use smart-garments and cabling: enabling the integration of all sensors in a single wearable, adjusted for different female and male body types.

Objective 1.4: To perform standardization activities regarding the developed electronics

Objective 1.5: To integrate off-the-shelf external Bluetooth devices in the WELMO system

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Lung diagnostics with EIT feature engineering and machine learning methods

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Abstract— **Patients suffering from pulmonary diseases typically exhibit pathological lung ventilation in terms of homogeneity. Electrical Impedance Tomography (EIT) is a noninvasive imaging method that allows to analyze and quantify the distribution of ventilation in the lungs. In this article we present a new approach to promote the use of EIT data and the implementation of new clinical applications for differential diagnosis, with the development of several machine learning models to discriminate between EIT data from healthy and non-healthy subjects. EIT data from 16 subjects was acquired: 5 healthy and 11 non-healthy subjects (with multiple pulmonary conditions). Preliminary results have shown accuracy percentages of 66% in challenging evaluation scenarios. The results suggested that the pairing of EIT feature engineering methods with machine learning methods could be further explored and applied in diagnostics and monitoring and applications of patients suffering from lung diseases. Also, we introduce the use of a new feature in the context of EIT data analysis (Impedance Curve Correlation).**

III. Introduction

Lung related diseases represent some of the most common medical conditions worldwide (1). Moreover, they are among the most significant causes of morbidity and mortality and are responsible for a substantial strain on health systems (2). Most of these diseases can be characterized by increased ventilation inhomogeneity associated with the pathologically changed regional lung function. Therefore, parameters that translate these changes in lung function can be useful in the diagnostics and monitoring of such diseases.

Electrical Impedance Tomography (EIT) is a non-invasive, radiation-free, imaging technique generate bio-impedance images/maps (3,4). Hence, the reconstructed images represent the electrical permittivity and conductivity distributions inside the chest (4).

The main objective of this exploratory study is to understand if the association of EIT and machine learning could be useful for differential diagnosis applications, through the employment of multiple traditional machine learning classification models. To the best of our knowledge, this is the first study where EIT data is employed in association with a machine learning classification pipeline, for this purpose. Therefore, we studied whether EIT derived measures of spatial and temporal ventilation homogeneity, extracted from periods of tidal and deep breathing, were able to discriminate between EIT data coming from healthy and non-healthy subjects.

IV. Materials and Methods

The data collection process for this study was carried out in the pneumology service at the George Papanikolaou General Hospital of Thessaloniki, Greece. A total of 16 (6 female, 10 male) participants were considered in this study, which included 5 healthy and 11non-healthy subjects, respectively. The group of non-healthy subjects suffered from a wide range of conditions (such as COPD, asthma, pneumonia, etc.).

In this study, several EIT features were extracted at a global and regional level, based on several regions of interest. The features were extracted for each inspiration cycle individually, from each fEIT image and the corresponding impedance curves.

Using the extracted features several machine learning classification models were developed to discriminate between EIT data coming from healthy and non-healthy subjects.

Acknowledgment

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Identification and analysis of stable breathing periods in electrical impedance tomography recordings

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Abstract— **An automated stable tidal breathing period (TBP) identification method based on processing Electrical Impedance Tomography (EIT) waveforms is proposed and the possibility of detecting and identifying such periods using EIT waveforms is analyzed/studied..**

V. INTRODUCTION

EIT is a non-invasive functional imaging modality that makes continuous chest examinations possible without any radiation exposure. EIT has been used mainly in ICUs for mechanically ventilated patients. These patients do not move and their ventilator-controlled breathing pattern is stable. Recently, the development of wearable EIT systems provided the possibility of monitoring regional lung ventilation in patients with chronic lung diseases, outside ICU [1,2]. These patients breathe spontaneously, and thus, their breathing pattern is not stable. Effects like body movement, speech, cough, sigh, exercise, change/loss in electrode contact impact the recordings and impose great challenges in automated EIT data analysis [1].

VI. METHODS

We analyzed 69 ten-minute recordings of EIT data collected from 10 lung-healthy adult subjects (4 men, 6 women). The data was recorded with the Goe-MF II EIT system (CareFusion, Höchberg, Germany) at 33 images/s. The examined subjects were instructed to perform different ventilation and non-ventilation manoeuvres during the data acquisition. These included: deep breaths, coughing, talking, laughing, change in posture (seated to standing and vice versa, torso rotation), eating. Raw EIT images were reconstructed using the GREIT algorithm. To isolate the breathing component of the global impedance waveform (GIW) low-pass filtering was used. The identification of the stable tidal breathing periods (TBP) was based on the breath-by-breath analysis of the amplitude of ventilation-related signal variation, representing the tidal volume, end-expiratory impedance level variation and the variation of the respiratory cycle duration using a sliding window algorithm. The ventilation homogeneity of these detected TBPs was characterized by the coefficient of variation of the above features.

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VII. RESULTS

The proposed stable tidal breathing method was applied to 69 ten-minute EIT recordings. In total, from 315 true TBPs, 288 TBPs were correctly identified (true positives) giving a success rate equal to 91.4%. The number of false positives (not stable TBPs that were identified as stable) was 48. The size of the sliding window was set to 6. The main sources of false positives in TBPs were speaking, eating and 'both arms elevation' posture.

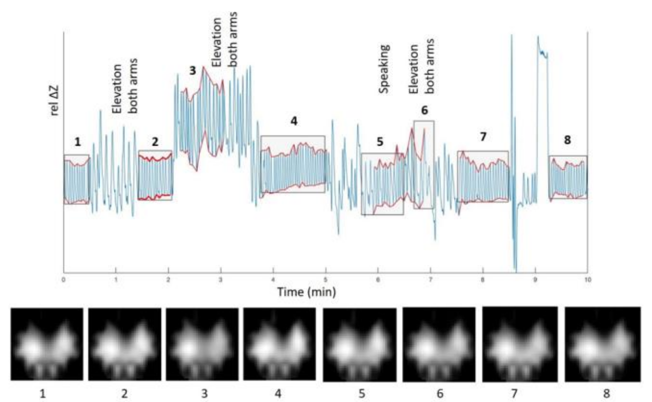

Figure 1. Stable Tidal Breathing Period identification result for a 10-min EIT recording session. (Top): The seven true TBPs identified by the expert are indicated by enclosing rectangles while the eight algorithmically identified TBPs by a pair of red lines connecting the end-expiration and end-inspiration points of their respiratory cycles (breaths). (Bottom): The corresponding average TV functional EIT images for each TBP.

VIII. DISCUSSION & CONCLUSION

Automated selection of undisturbed, stable TBPs based on the analysis of GIW is feasible when spontaneously breathing subjects are monitored by EIT. Specific activities during EIT recording may be false positive TBPs sources and should be avoided.

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The WELMO system architecture, design decisions for security, robustness and flexibility

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***Abstract*— While designing a modern respiratory data management system, functional requirements are not the only obstacles that must be taken in consideration. The WELMO system architecture focusses on the issues of security and deployment flexibility, aiming to provide a robust, future proof system that is able to tackle possible scalability, performance and accessibility demands with minimal effort.**

IX. INTRODUCTION

For the needs of the WELMO project the deployed software could be deployed in a single machine managing acquisition from the WELMO sensor vest, analysis of data and presentation to the HCP. The designed component-based WELMO system can be deployed either in a local setting, where the patient/WELMO vest and the HCP are on the same location along with the hardware and software that manages, analyzes and presents the data, or in an edge computing paradigm where the main functionality is local and only resource intensive operations are handled by cloud components, or, even, in a scenario that the patient is monitored remotely and all the services are deployed in the cloud.

X. RESULTS

Five components have been identified in WELMO: Two hardware components, the WELMO sensor vest (that acquires chest signals) and the external portable medical devices (that measure additional parameters such as SpO2), and three components that host the WELMO system software.

1) The WELMO Connector: this component contains the Patient app and the WELMO connector service sub-components. The WELMO connector service is responsible for the wireless/ acquisition of the signals recorded by the WELMO VEST, the wireless acquisition of the measurements from the External Devices and the synchronization/transfer of all the data to the WELMO Back-end.

2) The WELMO Back-end: this component consists of the Data Management, the Signal Analysis, the Authentication & Authorization sub-component and the Application Server. The authentication server provides the security mechanisms of the system and additionally stores all sensitive private data regarding the patient, thus allowing secure deployment of the rest components outside the local setting if needed. The data management is the sub-component responsible for managing the signals/health data by providing RESTful WEB services to store and retrieve signals/data. The Signal Analysis sub-component is responsible for the analysis of lung signals (both EIT and sound) to extract features and qualitative indicators about the patients' condition to provide explainable decision support. Finally, the Application Server is responsible for hosting the HCP application server-side functionality.

3) HCP PC: this component supports the HCP app where the HCP registers the patients and can review the session reports that include the signals recorded during a session along with analysis results provided, in a modern dashboard based clinical DSS.

The WELMO Data Management component is based on standards (HL7 FHIR) and may interface with external components (such as the hospital HIS) for data exchange if needed. The secure and authenticated connections among all the software the components along with the distributed functionality of the WELMO back-end in several separate sub-components can allow easy scalability of the most computation intensive system part, particularly in a possible cloud deployment (see diagram).

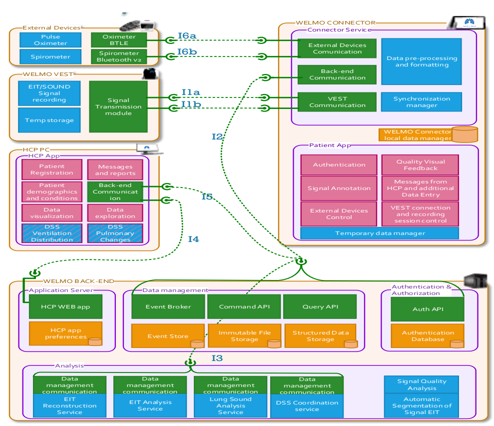

Figure 2. WELMO reference architecture diagram

XI. DISCUSSION & CONCLUSION

The presented system provides a paradigm for a modern respiratory data management approach where security, scalability and flexibility in deployment settings is needed.

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