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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of morbidity and mortality in the world, and leads to a substantial burden on healthcare services. Effective and timely management of patients with COPD has been essential to alleviate COPD exacerbation, improve the quality of life, and consequently reduce the economic burden. To achieve this, we propose an innovative tele-medicine system based on Smart Breath Analyzer (SBA) device and devoted to the tele-monitoring of exhaled air in patients suffering chronic respiratory failure and home-assisted by mechanical ventilation. In this work the main characteristics of the developed tele-medicine system are presented together with preliminary pre-clinical test results. The preliminary tests demonstrated the effective possibility to enter the SBAs in medical practice in home-ventilo-therapy protocols by suitable interpretation of the monitored

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Keywords Smart healthcare · Tele-medicine · Noninvasive Mechanical Ventilation · COPD Breath analysis · Gas sensing

1 Introduction

Chronic diseases (CD), also known as non-communicable diseases (NCD), are the leading cause of mortality in the world, accounting for a 71% of all deaths globally. The main types of CD are cardiovascular diseases, cancers, respiratory diseases, and diabetes which lead to 17.7 million, 8.8 million, 3.9 million, and 1.6 million deaths annually, respectively (WHO 2018). In particular, chronic respiratory diseases contributed 8,96% of NCD deaths in 2016, with chronic obstructive pulmonary disease (COPD), a highly prevalent disease characterized by persistent respiratory symptoms due to airway and/or alveolar abnormalities, leading to the most deaths from these conditions, with 2.93 million deaths (GBD 2016 Causes of Death Collaborators 2017). COPD is reported to have an estimated disease burden of 210 million people worldwide (WHO 2018) and results in high societal healthcare expenditures and resource utilization (Adeloye et al. 2015; Kim et al. 2016). In the European Union, the total direct costs of respiratory disease are estimated to be about 6% of the total healthcare budget, with COPD accounting for 56% of the cost of respiratory disease (American Thoracic Society Foundation 2014). Moreover, COPD exacerbations, considered the major determinants of health status in COPD, account for the greatest proportion of the total COPD burden on the healthcare system (GOLD 2018). Therefore, an optimal treatment is important in order to reduce the risk of exacerbation thus reducing the frequency of hospital admissions (Wedzicha et al. 2014).

Therefore, it is fundamental to face such global emergency by providing strategies for an effective management of COPD; the main aim is to improve monitoring and long-term management of the disease in primary care by increasing the availability and usage of interventions that can reduce the risk of hospitalizations, delay progression of the disease, prevent exacerbations, etc. (Polverino and Celli 2018). In this regard, emerging sensor technologies as well as telehealth care systems aim to be useful tools as support to diagnosis and exacerbations monitoring (Domingo et al. 2010; Dixon et al. 2016).

Considering the state of art of healthcare systems by which National Health Services organize the long-term home assistance of patients that need non-invasive mechanical ventilation (NIV), in this work we propose an innovative tele-medicine system based on Information and Communication Technologies (ICT) and in particular on the Internet-of-Things (IoT) paradigm, to increase the integration between hospital and territory health services in order to improve patients' health-related quality of life and exchange at distance information useful for patient monitoring.

This work is part of an Italian regional project (acronym project ReSPIRO: Rete dei Servizi Pneumologici: Integration, Research & Open- innovation) (http://respiro.eresult.it). The ReSPIRO project goals are 1) managing the pathology through the integration of care pathways considering the interactions between hospital, clinic, general practitioner, integrated system of social assistance and role of caregivers; 2) patient remote monitoring by continuous monitoring of respiratory gases (CO_2 and O_2) concentrations in exhaled air related to the patient health state during home-assisted non-invasive mechanical ventilation sessions. In relation with the first objective, ReSPIRO project proposed a new socio-health model able to overcome what is still in force today in Apulia by Italian Health Service for patients suffering

COPD; the model integrates hospital and home care by an assistance protocol involving clinicians, hospitals for nursing home assistance and companies in charge of technical assistance for NIV. In the Italian scenario, the project responds to a need expressed by both the Ministry of Health and the Apulia Region, which require an integration between hospital and territorial assistance as a model to be followed and implemented. In Apulia, in particular, the Brindisi local health agency has already started testing some programs of hospital-community integration and has expressed interest in using the ICT to foster hospital-territory integration. This integration requires data and information from *ad-hoc* sensors for monitoring the patient's health state and anticipating worsening of health condition.

As regards the second objective, on which our work is focused, we present a novel tele-medicine system consisting in an innovative and very low-cost electronic device called *Smart Breath Analyzer* (SBA), universally compatible with any mechanical ventilator set for bi-tube breathing circuit, that gathers some useful parameters from the patient’s exhaled air and sends monitoring data to a remote storage server for automatic processing. Physicians and healthcare staff can take advantage of this system in order to remotely check the effectiveness of the therapy and assess any events of exacerbation, thus enhancing the patient’s quality of life and reducing the healthcare service’s costs. In this work the main characteristics of the developed tele-medicine system are presented together with preliminary pre-clinical test results. The following sections highlight the various aspects related to the design and realization of this new tele-medicine system, emphasizing the technological aspects and the potential impact over the current COPD treatment.

2 The *ReSPIRO* tele-medicine system

2.1 Overall system architecture

The ReSPIRO tele-medicine system is a distributed hardware/software infrastructure, whose aim is to fill the gap between healthcare services and home-assisted COPD patients who need continuous monitoring looking forward to the prevention of disease exacerbations. The system diagram is depicted in Fig. 1:

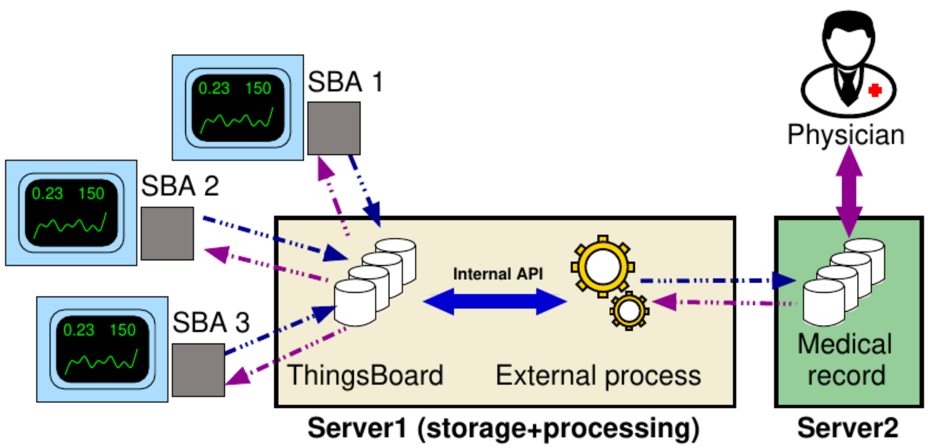

Fig. 1 - ReSPIRO tele-medicine system diagram. The picture shows a representative scenario with more Smart Breath Analyzer devices (three SBAs as example) inserted side-stream to the expiratory line of ventilator's bi-tube breathing circuit; SBA send data to Server 1 communicating with Server 2.

The system is designed to receive data from more SBA devices, installed at home of patients under non-invasive mechanical ventilo-therapy. The SBA is a module independent from ventilator; it is inserted side-stream to the expiratory line of bi-tube breathing circuit. The coupling of a SBA to breathing circuit makes it a supplementary universal module compatible with any commercial mechanical ventilator arranged for bi-tube breathing circuit. The device acquires sensor data and sends them, via TCP/IP communication, to an ICT remote platform. In particular, SBAs devices perform a bi-directional communication through MQTT protocol, a well-known protocol suited for embedded devices, with a first remote server (server 1) for storage and signal processing. Server 1 hosts both an IoT platform for interfacing the domiciliary SBAs devices to the database, and an external application process for data processing and analysis. As regards to the IoT platform, our choice fell on *ThingsBoard* since it is a 100% open-source IoT plaform enabling real-time data visualization (IoT Dashboards) and device connectivity via industry standard IoT protocols (like MQTT and HTTP); useful technical support with transport encryption is also available on web community. Although ThingsBoard is an excellent storage server, it provides only simple aggregation operators such as minimum, maximum, average value, sum and others and it doesn't allow more complex data analysis or aggregation. For this reason, we implemented an external application process that retrieves data from ThingsBoard, performs some basic computations like filtering and delivers processed data by means of *REST* services to the medical record software located on an additional server (server 2), a multifunctional IoT platform (*OMNIACARE*™, eResults srl, Italy) managed by the territorial hospital unit of Italian National Health Service (*ASL – Azienda Sanitaria Locale*). The different functional components of tele-medicine system are detailed below.

2.2 Smart Breath Analyzer (SBA) device

The SBA device is the key element of innovation in the ReSPIRO network and basically is a custom designed electronic device that includes a bunch of components to monitor various signals from sensors exposed to exhaled air, the electronic circuitry for signal conditioning and the fluidic components (sensor cell and gas lines) allowing the connection in side-stream to the expiratory line of the bi-tube breathing circuit (Radogna et al. 2018). The SBA device has been carefully designed with the target of minimizing air leaks in device gas lines thus allowing the ventilator's normal operation and ensuring the patient's safety. The SBA hardware architecture is schematized in Fig. 2.

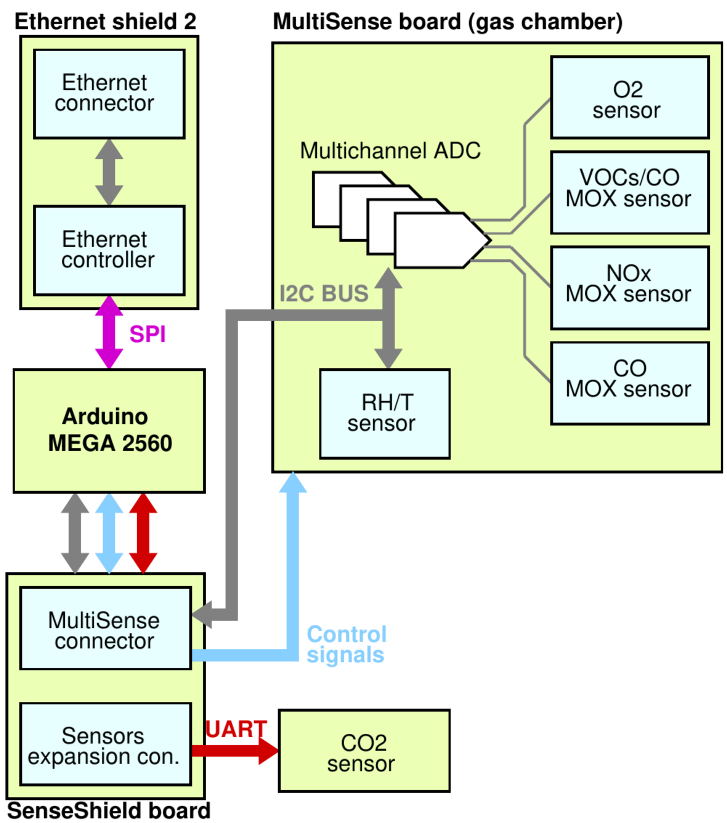

Fig. 2 Smart Breath Analyzer architecture.

The system hardware is designed to be fully compatible with *Arduino Mega 2560*, a well-known development board whose features are: low-cost development platform, good availability on the worldwide market, easy development thanks to a freely available Integrated Development Environment (IDE) and a large compatibility with a growing number of expansion boards, called *shields*. They allow Arduino to broaden its basic functionality through additional hardware such as communication shields (Ethernet, WiFi, Bluetooth and many others), relay shields to drive directly high power loads, motor driver shields and others. In particular, the Ethernet 2 shield was chosen to allow TCP/IP communication. Two custom printed circuit boards (PCBs) were designed and realized: the former, called *SenseShield*, was designed to be a sort of Arduino Shield; it offers a bundle of connectors for I2C and UART sensors and hosts a basic circuitry for voltage conversion from 5V (Arduino supply voltage) to 3.3V. The *SenseShield* board also hosts the connector for the second custom-designed board called *MultiSense*. The latter is the heart of the SBA device that includes all sensors except the infrared CO_2 sensor, all the interfaces and signal conditioning circuitry and the gas tight chamber. The device monitors the exhaled air through the following sensors:

- Infrared Carbon Dioxide (CO_2) sensor;
- Electrochemical Oxygen (O_2) sensor;
- Temperature & relative humidity sensor;

Moreover, a small electronic nose (e-nose), consisting in an array of three different MOX (Metal Oxide) based sensors, was added to the device sensing components. E-nose technology, known for its numerous applications in air quality and food industry, is also emerging as novel medical device for non-invasive screening and/or diagnostics for several pathologies (Wilson 2011) included respiratory diseases (Dragonieri et al. 2017; Finamore et al. 2018; Gasparri et al. 2018) and recently also patient monitoring in healthcare (de Vries et al. 2015). Alongside O_2 and CO_2, a multitude of Volatile Organic Compounds (VOCs) also passes from the blood into the lungs extremely efficiently. These VOCs are exhaled and provide a source of useful biomarkers directly linked to the body's metabolism. VOC profiles can be assessed using pattern recognition analysis, resulting in exhaled molecular fingerprints (*breathprints*). The challenge is to integrate a low cost e-nose technology with existing diagnostic tests, such as routine spirometry or NIV, in order to bring this technology to 'point-of-care'.

E-noses need training and study design on population classes; breathprints related to known cases and controls has to be acquired to build a database by which pattern recognition algorithms can be trained, so that unknown compounds can be subsequently classified and identified. The e-nose technology has been already used with success in this application field, i.e. it has been showed that through the analysis of VOCs fingerprint in exhaled breath by e-nose it is possible to discriminate patients with lung cancer from COPD patients as well as healthy controls (Dragonieri et al. 2009) as well as in early clinical diagnosis of many diseases (Wilson 2017).

All the sensors are enclosed in a properly designed gastight cell made of Polyoxymethylene (POM), a thermoplastic suitable for the application; only the infrared CO_2 sensor was connected in series with sensor cell. The device firmware has been designed to accomplish both the sensor acquisition/control task and the communication task, as depicted in Fig. 3.

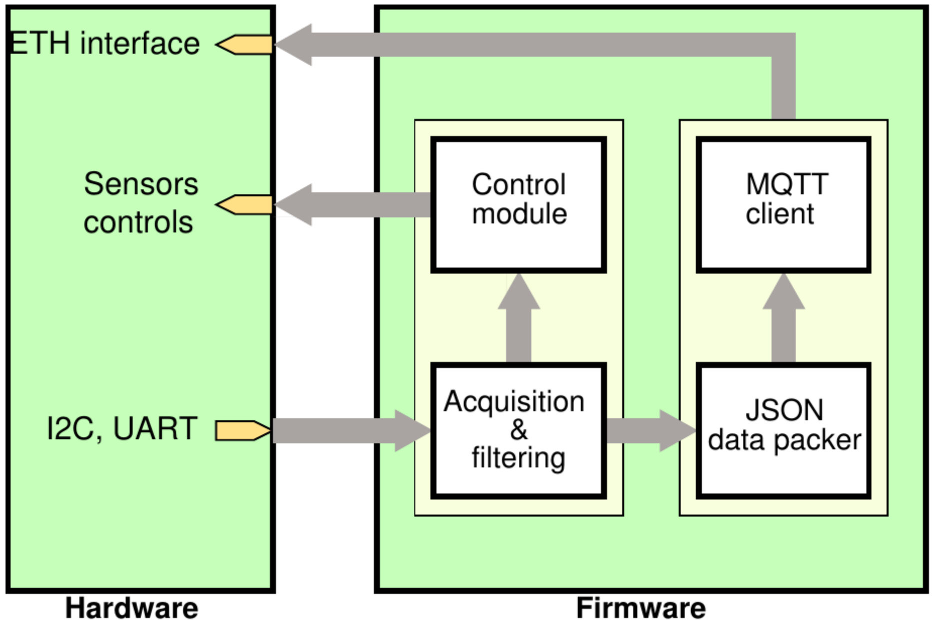

Fig. 4 Smart Breath Analyzer firmware architecture.

The communication protocol adopted for data communication is MQTT, a well-known publish/subscribe-based messaging protocol especially suited for low-resource embedded systems and for applications in which the network bandwidth is limited. Besides network protocols, another important aspect for the performance of IoT communications concerns data exchange formats. Some older REST services adopted the XML format to transform the received messages into viewable web contents through XSL sheets (De Luca et al. 2011, De Luca et al. 2012). Nowadays, JavaScript Object Notation (JSON) is preferred to Extensible Markup Language (XML) mainly due its better readability; it is widely adopted even in place of binary encodings, which could provide better performance for IoT devices (Lampesberger 2016). Furthermore, despite JSON has higher computational requirements of encoding and decoding operations, it is generally faster than XML. Moreover, although the memory usage between the two formats is comparable, the CPU usage is higher for JSON, even if it doesn't depend on the amount of encoded objects (Nurseitov et al. 2009).

SBA devices send sensor data over MQTT as telemetries, which are time series of key-value pairs encoded as JSON strings. ThingsBoard gathers such data following a sequential window algorithm in which each sensor has a dedicated time slice to acquire a fixed number of samples. For every sensor acquisition value an acquisition timestamp is associated in order to follow at least one complete respiratory act for every sensor with the best time resolution. The arithmetic mean is computed for each parameter to aggregate all the values within the same sampling window. Such aggregated values will be used to estimate the trend of the monitored parameters by means of control charts.

The designed Smart Breath Analyzer was realized in all its components and inserted side-stream by means of two standard Tee-connectors in the expiratory flow of a bi-tube breathing circuit connected to a mechanical ventilator. In Fig. 5 a picture of the SBA device, properly connected to bi-tube breathing circuit at hospital setting, is reported.

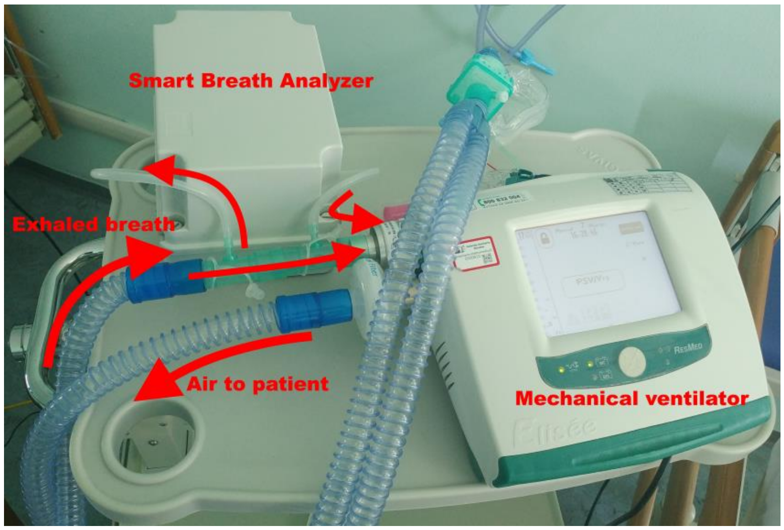

Fig. 5 A SBA device connected to bi-tube mechanical ventilator used in clinical practice.

2.3 Data collection and analysis

The developed SBA devices fall within the context of the so-called Internet-of-Things, a paradigm in which almost every object (the "things") can be connected to the Internet with a univocal address to exchange data between the application field and a remote platform for data storage and analysis. Several software platforms have been developed to provide an abstraction layer that should hide technical details of heterogeneous IoT hardware. IoT platforms can be classified into three categories (da Cruz et al. 2018):

- device management platforms, which handle device management and try to optimize network resources;
- application development platforms, which address security, scalability and heterogeneity issues;

- application enablement platforms, known as IoT middleware platforms, which provide data management and visualization and allow the integration with external applications.

IoT middleware platforms generally support MQTT, CoAP and other resource-constrained protocols for device communications and expose REST services as interfaces to external applications. As mentioned earlier, for the ReSPIRO project we chose ThingsBoard (De Paolis et al. 2018) an IoT platform based on Java 8 that can collect data from several devices through the HTTP, MQTT and CoAP protocols. It supports QoS level 0 (at most once) and QoS level 1 (at least once) for MQTT. It provides a web interface for registering and managing devices and the possibility to create rich dashboards updated in real-time for data visualization. For each device it allows to store configuration properties and information about technical features in the form of attributes. It stores data received from devices as telemetries, which are time-series of key-value pairs of data. Moreover, ThingsBoard provides REST API to manage devices and fetch data from telemetries and a REST plugin to send HTTP requests to external endpoints.

The analysis on how monitored parameters change over time is performed by means of control charts, implemented in a separated application process running on the same server machine of ThingsBoard (equipped with a Core i7 processor and 8 GB of RAM). Control charts are a useful tool to monitor parameters in a process of whatever nature, determining whether a process is stable or not by detecting variations generated by special causes. The medical record software (OMNIAPLACE, eResults srl), hosted on the server 2 at the Local Health Authority and managed by the same authority, periodically forwards REST/HTTPS requests to server 1 to receive aggregated data and control chart outputs and evaluate them from a clinical point of view. The external process running on server 1, based on the Java Spring framework, receives REST requests from server 2 and exploits ThingsBoard REST API to retrieve the time series of raw data sent by devices. It produces an output JSON string containing a subsection for each monitored parameter, where the outputs of three different control charts are encoded.

While problems related to device operations are already monitored and reported to the operators, the main expected result is to generate appropriate alarms reporting problems related to the patient's health status (an exacerbation of clinical conditions can be predicted in advance and doctors can be warned in time). Finally, OMNIAPLACE integrates all the data retrieved from server 1 (i.e. aggregated data and control charts outputs) into a patient's electronic medical record (EMR). The EMR on OMNIAPLACE was suitably designed for COPD patients to systematically and electronically store health information in a digital format capture the patient state across time.

2.4 Control charts approach

Control charts were originally introduced by Shewhart to control manufacturing processes (Shewhart 1931). Nowadays, they are employed to monitor various parameters in several application fields. In particular, they are widely adopted for monitoring clinical variables (Tennant et al. 2007). In the Shewhart's chart, also known as P-chart, there is a central line represented by the arithmetic mean (μ) of parameter values and upper and lower lines represented by μ+3σ and μ-3σ, where σ is the standard deviation. The parameter is considered stable when the measured values fall within these limits.

Various other charts (Thaga and Sivasamy 2015) have been proposed as alternatives to the original Shewhart's chart: most of them simply differ in the models employed to compute the central line and the upper/lower bounds. Besides the P-chart, we implemented the G-chart and the EWMA chart. The G-chart (Riaz and Saghirr 2007) of a monitored process X, represented by n samples $x_1, \dots, x_n$, is based on the central line and the upper/lower limits computed for the variable:

$$K = \left(\frac{\sqrt{\pi}}{2}\right)[(\sum_{\substack{j=1 \\ j\neq i}}^{n}\sum_{i=1}^{n}|x_i - x_j|)/(n(n-1)/2)]$$

The EWMA chart (Roberts 2000) is based on the Exponentially Weighted Moving Average of the monitored process Y (with mean μ_Y and standard deviation σ_Y), defined as $W_i = \lambda Y_i + (1-\lambda)W_{i-1}$, where $0<\lambda\leq 1$ is the smoothing parameter and $W_0=\mu_Y$. The central line and the upper/lower limits for W can be defined as:

$$CL = \mu_W$$

$$UL = \mu_W + L\sigma_W = \mu_Y + L\sigma_Y\sqrt{\frac{\lambda}{2-\lambda}(1-(1-\lambda)^{2i})}$$

$$LL = \mu_W - L\sigma_W = \mu_Y - L\sigma_Y\sqrt{\frac{\lambda}{2-\lambda}(1-(1-\lambda)^{2i})}$$

We chose λ=0.05 and L=2.646. While the P-chart, based on arithmetic mean, gives the same importance to all the values within an aggregation interval, the EWMA-chart gives more importance to more recent values.

In our implementation, the aggregated values, represented by the central lines, are computed for each control chart on some configurable moving temporal intervals expressed in hours. In the JSON respective section, a STABLE, UP or DOWN property is setup if a parameter value falls within, above or below the variability interval determined by the upper and the lower limits. We obtain a reply from the server in just few seconds when we request patient data collected during two weeks.

3 Clinical trial planning

A clinical trial on a small cohort of patients suffering COPD and receiving NIV therapy has been planned by using the ReSPIRO tele-medicine system. The trial will be carried out during patient's ventilo-therapy sessions both in out-patients department under the supervision of a pneumologist and in-home settings.

3.1 Study design

The observational study related to the planned clinical trial was approved by Ethics Committee of Local Health Service Unit of Lecce and Brindisi. Prior to participation in the study, all subjects will provide written, signed, informed consent. COPD patients with GOLD (Global Initiative for chronic Obstructive Lung Diseases) stage IV (GOLD 2018) admitted to Pulmonary Department of the "Fazzi" Hospital (Lecce) and "Perrino" Hospital (Brindisi) will be recruited by the pneumologists of these Health Units according to the following inclusion and exclusion criteria.

Criteria for selection include one or more risk factors of exacerbation: (a) age > 50 years, (b) smokers or ex-smokers, (c) presence of comorbidities, (d) inspiratory capacity/total lung capacity (IC/TLC) < 25%; (e) one or more COPD exacerbations in the last year; (f) female sex; (g) occupational exposure to harmful substances (dust, fumes, chemicals) and/or environmental pollution. Patients with neuromuscular disorders or, based on the pneumologist evaluation, problems that interfere with the outcome of our study will be excluded.

Mechanical ventilation parameters will be set for each patient according to the specific therapeutic/ventilatory prescription at hospital's discharge and his/her personal pulmonary compliance ensuring patient comfort during ventilo-therapy session. Generally, ventilation parameters include: ventilation mode (CPAP, BILEVEL-S, BILEVEL ST, PCV, (A)PCV, PSV-TV), expiratory positive airway pressure (EPAP), inspiratory positive airway pressure (IPAP), respiratory rate (RR), inspiratory time

(Ti), inspiratory time per minute (Ti min), inspiratory trigger (Trig.I), expiratory trigger (Trig.E) and oxygen flow (O_2). Clinical guidelines recommend starting with low levels of pressure (IPAP: 8–10 cmH2O; EPAP: 3–4 cmH2O) and progressively increasing pressure according to patient adaptation capacity (Mas and Masip 2014).

In the clinical trial the BILEVEL ST ventilation mode will be applied to patient's cohort, i.e. spontaneous / timed (S/T) mode via oronasal mask and with double-tube circuit (with one inspiratory and one expiratory line) using a bi-level positive airway pressure system.

We will also verify that the displayed tidal expiratory volume (V_{te}) and minute volume (V_m) values are in normal range not altered by the insertion of the device in the patient breathing circuit.

Arterial-blood gas analysis will be determined in all patients: a) at the recruitment stage to register the patient basal values (baseline), b) during each NIV session, and after the study, i.e. at the end of the prescribed NIV therapy, to check the individual benefit of NIV on patient health state. In the blood samples, parameters of PH, arterial partial oxygen pressure (PaO_2) and arterial partial carbon dioxide pressure ($PaCO_2$) will be recorded on patient's electronic medical. PaO_2 and $PaCO_2$ will be correlated with the exhaled O_2 and CO_2 concentration (ExO_2 and $ExCO_2$) monitored by the developed SBA in the expiratory air and elaborated according to control charts approach. Such elaborated data from the SBA will reach the OMNIACARE IoT platform allowing the pneumologist to join the clinical data contained in EMR with the complementary information provided by the monitored ExO_2 and $ExCO_2$. This will allow the doctor to have an additional monitoring tool to assess the patient's status during NIV by performing a physiological interpretation of the device data corresponding to an altered respiratory function.

3.2 SBA functional tests

The functioning of the SBA device and the implemented firmware for sensor sampling procedure were verified by functional tests. Some first functional tests were carried out in local without sending the data to the developed remote server architecture, in order to differentiate the control of a correct data acquisition from the possible problems that may occur in data transmission. Hence, the data were sent (via device USB port) to the serial port of a PC. A healthy volunteer, accepting to undergo a noninvasive ventilo-therapy session, was recruited; for volunteer safety, the ventilator parameters in BILEVEL ST mode have been set according to the pneumologist's indications. Fig.5 reports the temporal registration of all the sensors tracings according to the sequential sensor sampling protocol.

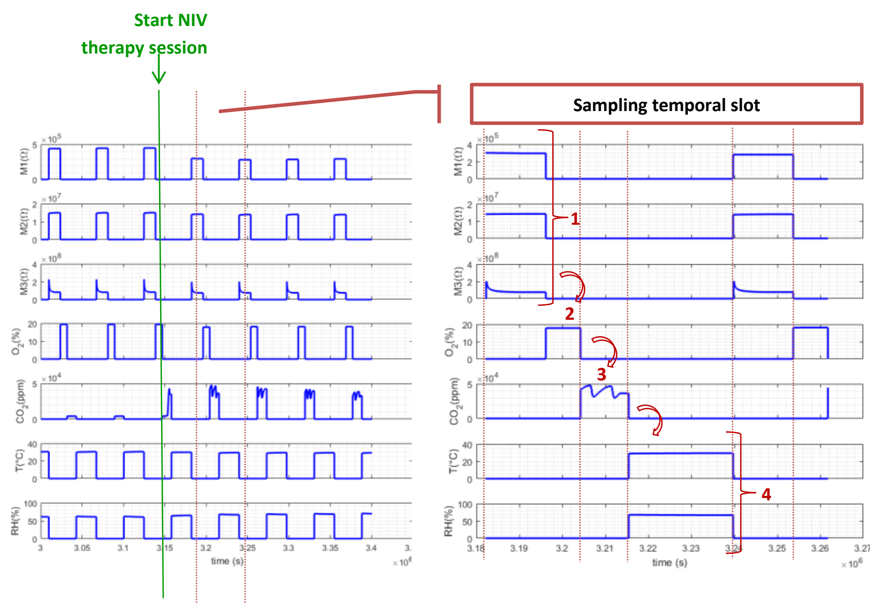

Fig 6 - Breath signals taken in a functional test in local from an healthy volunteer.

As it can be observed, the sampling protocol, according to which the sensors are sampled one at a time, works correctly; step1: signal sampling from 3 MOX-based sensors (sensor resistance M1, M2 and M3 in Ohm); step 2: signal sampling from O_2 sensor (O_2 concentration in %); step 3: signal sampling from CO_2 sensor (CO_2 concentration in ppm ($\equiv 10^{-4}$ %)); step 4: signal sampling from R.H. & T sensor (R.H. in %; T in °C). As expected, the O_2 concentration decreases and CO_2 concentration increases from inspiratory values to physiologic exhaled values for a healthy subject. The signals from MOX-based sensors also changed toward lower resistance values indicating a promising sensitivity to exhaled VOCs. Humidity content in exhaled air is typically high (≈90 %) and an increase of R.H. was indeed registered during the NIV session compared to the value before the start. The acquired sensor traces collected from all the sampling windows for each sensor are hence valid for a next data analysis and correlation with routine clinical examinations and clinical data. Of course, an appropriate suitable interpretation of the monitored parameters by a physiological point of view is required.

4 Conclusions

In this paper, a tele-medicine system, based on Smart Breath Analyzers (SBA) was designed, realized and verified in laboratory by functional tests. The SBA star-based network system has the aim to fill the gap between healthcare services and COPD patients that relies on home-assisted mechanical therapy to cope with the disease. The preliminary functional tests demonstrated the effect possibility to enter the SBAs in medical practice in home ventilo-therapy protocols by suitable interpretation of the monitored parameters by a physiological point of view. Thanks to a network composed by many SBA devices that send patients data to a remote server, the doctor can tele-monitor the status of the patient in order to check any state of exacerbation of the disease. The remote server can process, in real-time, the incoming data from devices to predict the exacerbation of the disease. Indeed, COPD exacerbations further complicate the management of the disease since they lead to critical worsening of patient's health status, hospitalizations and readmissions, and disease progression (Wedzicha JA et al. 2007). In this context, it is fundamental for clinicians to get health and medical information from patients when they are at their homes in order to provide them with care services and deliver effective and safe clinical interventions and treatments, which can be limited in the traditional nurse-visit programs (Ding et al 2012; Bourbeau and Farias 2018).

At the moment, in the territorial area of Apulia region, there is no integrated program of intervention on the territory aimed at ensuring proper management of the various levels of disease severity. In consideration of this requirement of the regional national service of the Apulia region, we proposed the monitoring of patients in their homes through devices and sensors, which, if implemented in a capillary way, can be able to signal in real time (alarm signal) to Local Health Authority the incurrence of actual exacerbations of the disease, requiring intervention by health personnel.

This telemedicine system model has many strengths. The intervention can be tailored to patients' needs and clinical status in order to attain the comfort of subjects. The use of sensors and devices, which may perform a patient's breath analysis, would allow the double advantage of preventive and non-invasive control of respiratory function by managing and/or delaying the evolution of chronic respiratory problems, with predictable social and economic impacts.

The telemedicine system aims also to advance industrial research and technological transfer in the field of Ambient Assisted Living because it could improve the life of home-assisted COPD patients and reduce the related costs of healthcare services. Finally, we aimed to link multi-professional collaborative teams to deliver home care services, that is essential to ensure quality of care, and is challenging in traditionally home care programs.

Despite these advantages, we have to mention some controversial opinions regarding the effective cost/benefit of a telemedicine scenario. For example, integrating telemedicine into practice allows clinicians to intervene earlier and prevent complications, but it may increase the alarm frequency and the intervention requests to be managed with an even greater burden on National Health Service system. (Ambrosino et al. 2016). Moreover, the legal problems associated with telemedicine are still controversial. Economic advantages for healthcare systems, though potentially high, are still poorly investigated.

To recap, the key findings obtained by preliminary pre-clinical results indicate that the application of this innovative telemedicine system will lead to improved clinical outcomes in terms of early detections of exacerbations and improved quality of life in COPD.

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