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Publishing system for continuous and remote monitoring of patients receiving Home Mechanical Ventilation

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Abstract. Home Mechanical Ventilation is the treatment of patients with insufficiency respiratory or failure by means of a mechanical ventilator at a patient's home. In order to allow remote patient monitoring, several tele-monitoring systems have been introduced in the last few years. However, most of them usually do not allow real-time services, as they have their own proprietary communication protocol implemented and some ventilation parameters are not always measured. Moreover, they monitor only some breaths during the whole day, despite the fact that a patient's respiratory state may change continuously during the day. In order to reduce the above drawbacks, this work reports the development of a novel remote monitoring system for long-term, home-based ventilation therapy; the proposed system allows for continuous monitoring of the main physical quantities involved during home-care ventilation (e.g. differential pressure, volume and air flow rate) and is developed in order to allow observations of different remote therapy units located in different places of a city, region or country. The developed remote patient monitoring system is able to detect various clinical events (e.g. events of tube disconnection and sleep apnea events) and has been successfully tested by means of experimental tests carried out with pulmonary ventilators typically used to support sick patients.

Keywords: pulmonary ventilation, non-invasive ventilation, home mechanical ventilation, telemedicine, e-health, remote patient monitoring

I. INTRODUCTION

Mechanical ventilation is the use of a mechanical ventilator to assist (or replace) breathing when a person is not capable of breathing sufficiently on their own, typically because of respiratory failure or insufficiency, caused by failures in the lungs or by failure in the pump mechanism (i.e. chest wall and respiratory muscles)^{1–2}. In the considered sicknesses, a mechanical ventilator provides a controlled flow of gas into the patient's lungs, with a certain differential pressure temporal pattern and with a certain value of temperature^{3–7}. During the aforementioned therapy performed in an intensive hospital care unit, ventilation parameters are monitored by physicians and nurses in order to evaluate patients' physical conditions.

Patients who have acute respiratory failure and who have not responded to other treatment options can benefit from using a treatment, called Home Mechanical Ventilation (HMV), performed by means of a mechanical ventilator at the patient's home⁸. Around 21,500 individuals are receiving home ventilation in Europe⁹; moreover, with reference to the prevalence of sleep disorders, it is

estimated that 4% of males and 2% of females suffer from obstructive sleep apnea (OSA) and the majority of patients are thought to be undiagnosed¹⁰. However, during the treatment of HMV, it is difficult for a physician to continuously monitor ventilation parameters and to evaluate the physical conditions of a patient. Indeed, during long-term, home-based therapy, intensive follow-up and close monitoring by caregivers are necessary to improve patient safety, particularly for children and patients in remote regions.

In order to reduce the considered shortcomings, the remote patient monitoring (RPM) technique can be used^{11–20}. This is a wide-range technology allowing the monitoring of patients outside of conventional clinical settings (e.g. in the home).

Indeed, in the last few years, several tele-monitoring systems have been proposed (e.g. both RPM systems embedded in home care ventilators and stand-alone devices which can be connected to ventilators); however, usually they do not provide continuous, real-time monitoring of ventilation parameters and do not measure various ventilation parameters. Moreover, they typically

Publicability only some breaths during the day (sample monitoring), but breathing conditions may vary very strongly during the day and from one breath to another. Furthermore, for a single breath, they usually only provide the values of some ventilation parameters (e.g. the value of the maximum ventilated volume, the peak flow, the "Inspiratory Positive Airway Pressure" (IPAP) and the "Expiratory Positive Airway Pressure" (EPAP)), but they typically do not make available the information typically monitored in ventilated patients in an intensive care unit of a hospital (e.g. temporal pattern of the air flow rate and the differential pressure during a single breath and for all daily breaths)²¹.

In order to reduce the above quoted drawbacks, the development of a new remote monitoring system for longterm home-based therapy is reported in this work; the proposed system is based on the continuous real-time monitoring of the main physical quantities involved during home-care ventilation (i.e. temperature, flow and differential pressure of air mass supplied by mechanical ventilator)¹⁻⁷ and is developed in order to allow observation of different remote therapy units located in different places of a city, region or country (Fig. 1). Finally, the proposed system is able to monitor each breath occurring during the whole day and provides the temporal pattern of the air flow rate and differential pressure during a single breath and for every breath occurring during the whole day and can detect various clinical events (e.g. events of tube disconnection and sleep apnea events). Two different system configurations have been developed; the first one is based on a wired connection, while the second is based on a wireless sensors network. Both configurations may be used with any kind of home ventilator, and indeed, the proposed system constitutes a module which is pneumatically connected to the patient circuit, as reported in the following Section II.

The developed RPM system has been evaluated by means of experimental trials carried out with pulmonary ventilators typically used to support sick patients. During these trials, the information on the treatment of HVM are provided to remote devices used by physicians, nurses and caregivers, allowing a continuous tele-monitoring both during a single breath and for every breath occurring during the whole day.

II. MATERIALS AND METHODS

The proposed RPM system is arranged with multiple Patient Ventilation Monitoring Units placed at the patient's home (Figure 1); each Patient Ventilation Monitoring Unit is based on a measurement system which is pneumatically connected to the pneumatic circuit placed between the home ventilator and patient. The measurement system consists of a data acquisition system (DAQ) which is connected to sensors for the detection of the main

parameters of pulmonary ventilation. The DAQ system samples data coming from sensors and sends them to a laptop, allowing signal processing and data transmission by means of the protocol TCP/IP. Then, measurement data from different remote home therapy units can be sent, by means of an Internet connection, to a server farm and, as consequence, to a remote team of physician and nurses, with the guarantee of information security and patient privacy (authentication is needed in order to access to measurement data). In particular, all measurement data are provided to a Data Base Management System and ready to be made available to remote devices (PCs, tablets or smartphones) by using several applications (e.g. a Java desktop application and an Android application).

In the following paragraphs, experimental setups for the measurements of temperature T, flow Q and differential pressure ΔP are reported. Detailed specifications of sensors used at the Patient Ventilation Monitoring Unit of the system (named "MyVenus") may be found here²².

Moreover, the two different configurations of the Patient Ventilation Monitoring Units are described in Figure 2.

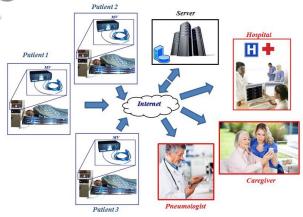


FIG. 1. Scheme of the proposed telemedicine system for home mechanical ventilation.

A. Temperature measurement

During the treatment of HMV, a heated humidifier is typically used to maintain a set air temperature and relative humidity in order to compensate for the natural conditioning of air by the respiratory system (e.g. during the therapy of HMV, air by-passes the nose and, as a consequence, its warming function) and to avoid pulmonary infections and lung tissue damage²³⁻²⁵. Therefore, the temperature of the air mass supplied is an important physical quantity to be monitored during pulmonary ventilation and is not always measured by current commercial RPM devices. Instead, in intensive care units, air temperature is monitored by means of a numerical indicator typically placed on the heated

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In this work, the temperature of the air mass supplied by a pulmonary ventilator has been monitored by means of the temperature sensor Texas Instruments LM35 (measurement range: from -60 °C to 150 °C, accuracy: ±1 °C, sensitivity: 10 mV/°C); the thermometer TI LM35 has been placed in a pipe in order to measure the air temperature supplied by mechanical ventilator.

As the range of temperature from 15 °C to 45 °C is sufficient to cover the values of air temperature typically encountered during the treatment of HMV, the voltage output of the Texas Instruments LM35 temperature sensor (between about 150 mV and 450 mV) has been amplified in order to better exploit the dynamic range of the DAQ. A voltage follower, developed by means of Texas Instruments OPA2277 operational amplifiers, has been used to transfer the output voltage of the LM35 temperature sensor to a second amplifier circuit constituted of the Texas Instruments INA128 (Figure 3).

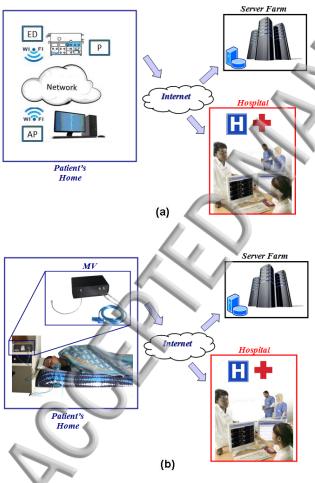


FIG. 2. Scheme of the proposed telemedicine system for home mechanical ventilation with comparison between two different configurations of Patient Monitoring Unit. (a) wireless configuration. (b) wired configuration. ED: end device; AP: access point; P: pulmonary

ventilator; MV: enclosure containing sensors and data acquisition card (wired configuration).

B. Flow measurement

Measurement of air flow supplied by a mechanical ventilator is performed by means of a heated pneumotachograph, PNT (resistance: 0.054 cmH₂O·min/l) connected to a differential manometer, DM (measurement range: from -0.63 cmH₂O to +0.63 cmH₂O, accuracy: 1 percent); the manometer DM has been powered with a +9 V. The heating element voltage pneumotachograph has been supplied by means of DC/DC converter TPS54233EVM-373 which has been used with an input voltage of +9 V (Figure 3). During the experimental trials shown in Figure 7 and Figure 8, measurement of air flow rate is performed by means of a variable orifice type flow sensor (resistance: 1.6 mbar/l/s) connected to the same above quoted differential manometer DM.

C. Differential pressure measurement

Measurement of respiratory pressure is performed by means of a differential pressure sensor, PS (measurement range: from 0 cm H_2O to +100 cm H_2O , accuracy: 5 percent.

D. Patient Ventilation Monitoring Unit

Each Patient Ventilation Monitoring Unit allows the acquisition, processing, visualization and transmission of signals. The output of sensors have been acquired with DAQ and are processed in a LabVIEW environment in order to obtain the main parameters of pulmonary ventilation from the temporal pattern of differential pressure and air flow rate (e.g. IPAP, EPAP, mean pressure, inspiratory time, breathing frequency, minute volume, tidal volume, peak flow). As the breathing rate typically encountered during pulmonary ventilation is up to 20 breaths/min and pulmonary ventilators typically support up to 200 breaths/min⁷, the sampling frequency has been set to 20 Hz per each measurement channel (i.e. air flow, differential pressure and temperature channels). Every 10 seconds, the Patient Ventilation Monitoring Unit transmits the measured and the processed data related to the last 10 seconds of monitoring to the server; each 10second package of transmitted data is about 7 kilobytes.

Two different configurations of Patient Ventilation Monitoring Unit have been developed and are reported in the following sections.

Publishing ient Ventilation Monitoring Unit: wireless configuration

In the first configuration of the proposed system, the ventilation monitoring unit placed at the patient's home is based on a wireless sensors network (Figure 2(a)), in which an Access Point (AP) manages the network and receives sampled data coming from an End Device (ED), which is connected to the sensors for the measurements of flow, differential pressure and temperature of the air supplied by a mechanical ventilator. The AP, which is connected to a laptop placed at patient's home, receives sampled data coming from the ED, connected to the wired electrical output of the sensorial units. The wireless sensor network has been developed by using the DAQ Texas Instruments eZ430-RF2500, constituted of AP and ED and based on a wireless connection using the network protocol named Texas Instruments SimpliciTI²⁶.

In the structure of the ventilation monitoring unit (wireless configuration, Figure 2(a)), the outputs of:

- the amplifier circuit for the temperature T measurement,
- the differential manometer DM, pneumatically connected to the pneumotachograph PNT (or to the variable orifice type flow sensors), for the air flow *Q* measurement,
- the differential pressure sensor PS for the measurement of respiratory pressure ΔP ,

have been connected to three different analog inputs of the ED (Figure 3). The ED includes a microcontroller and an Analog to Digital Converter in order to convert the analog signals coming from the electrical output of the LM35 amplifier circuit, DM and PS. Furthermore, the ED includes a transmitter in order to send measurement data to the AP, which includes a receiver device for the purpose of receiving measurement data coming from the ED. The AP is connected to a laptop where measurement data are stored and are ready to be sent to the server farm.

D.2. Patient Ventilation Monitoring Unit: wired configuration

In the second configuration of the proposed monitoring system, the ventilation monitoring unit placed at patient's home is based on a wired connection and differs from the wireless sensor network in the sense that the sensors' output for the measurement of air flow rate, differential pressure and temperature are connected by means of a wired link to a DAQ (10k sample per second; resolution: 12 bit; resolution; input voltage up to 10 V). Data acquired by means of a DAQ card are stored on a laptop and then sent to a server farm and to medical doctors, nurses and caregivers according to the scheme shown in Figure 2(b). The wired configuration of the Patient Ventilation

Monitoring Unit described here is based on the use of the variable orifice type flow sensor, which has no heated element and, as a consequence, does not require an external electrical current.

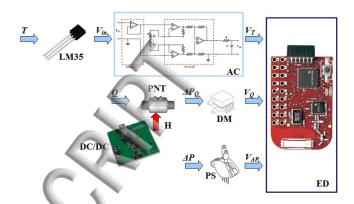


FIG. 3. Block diagram (not in scale). AC: amplifier circuit; DC/DC: TI TPS54233EVM-373 dc/dc converter; PS: pressure sensor; PNT: pneumotachograph; DM: differential manometer; W: wired connection to power supply unit and to the End Device; H: wired connection to the heater element of the PNT; ED: End Device.

III. EXPERIMENTAL SET-UP

The developed RPM system has been successfully tested by means of experimental trials during mechanical ventilation (Figure 4). The pulmonary ventilators used during experimental trials have previously passed a testing procedure; in the experimental setups shown in Figure 4(a) and Figure 5, a pulmonary ventilator for an intensive care unit (Carefusion Avea) has been used with a bi-tube connection; in the experimental setups shown in Figure 4(b) and Figure 6, a home ventilator (Respironics Trilogy 100) has been used with a mono-tube connection.

In accordance to the scheme presented in Figure 4(a) and Figure 5, the proposed RPM system (in the wireless sensors network configuration) has been tested during mechanical ventilation whereby a pulmonary ventilator V supplies a simulated load TL (neonatal/pediatric test lung) by means of a pneumatic circuit PC with a bi-tube connection. The air flow sensor has been placed between the Y-shaped element of the breathing circuit and the load TL in order to measure the air flow rate supplied by the ventilator to test lung TL; the pressure sensor has been arranged in order to measure pressure at the Y-shaped element; the thermometer LM35 has been used for the measurement of the temperature of the air supplied by the ventilator, V.





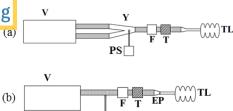


FIG. 4. Scheme of experimental setups (not to scale). (a) Trials with pulmonary ventilator with bi-tube connection. (b) Trials with a home ventilator with mono-tube connection. V: mechanical ventilator; PV: respiratory mask; Y: Y-shaped element of breathing circuit; TL: test lung; PS: pressure sensor; F: system for flow measurement; T: thermometer; EP: exhalation port.

The SimpliciTI Access Point (AP) receives sampled data coming from the SimpliciTI End Device (ED), which is connected to the above quoted sensors, and, as a consequence, data was visualized on the laptop. Experimental trials have been carried out in an environment with a mean temperature of 25±1 °C and a mean relative humidity of 55±5 percent (the measurement of air temperature and relative humidity have been performed by means of a thermos-hygrometer Fluke 1620A). Measurement data about temperature T, flow C and differential pressure ΔP have been managed with a frequency of 20 Hz per channel and have been acquired simultaneously. In the following, an experimental trial is reported and the main settings of the pulmonary ventilator used during the test are: pediatric patient; ventilation mode: volume assist control ventilation; tidal volume: 30 ml; positive end expiration pressure (PEEP): 4 cmH₂O; %O2: 21%. Measurement data acquired during the considered experimental trials are in accordance with the above quoted setting of the pulmonary ventilator used and are reported in Figure 6. However, the sampled data dealing with the temporal pattern of air pressure, flow and temperature can be processed in order to obtain other vital parameters related to mechanical ventilation (e.g. breath rate, inspiration time, positive end expiration pressure (PEEP), peak inspiratory pressure (PIP), mean pressure, peak flow, minute volume and tidal volume (Vt)) ²¹⁻²².



FIG. 5. Experimental setup for trials with a pulmonary ventilator with a bi-tube connection typically used in the intensive care units with wireless configuration of the Patient Ventilation Monitoring Unit. V: mechanical ventilator; Y: wye-shaped element of breathing circuit; TL: (neonatal/pediatric) test lung; P: pressure sensor; F: flow sensor (pneumotachograph); T: thermometer; ED: end device; AC: access point; SP: sensors platform; PC: patient circuit; W: wired connection between SP and ED.

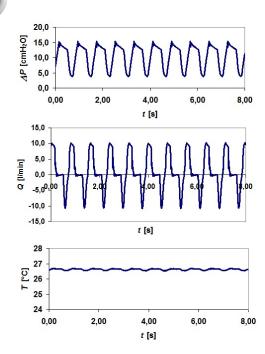


FIG. 6. Experimental results during an experimental trial with the pulmonary ventilator typically used in the intensive care unit showing the temporal pattern of differential pressure, air flow rate and air temperature.

In accordance to the scheme presented in Figure 4(b) and Figure 7, the wired configuration of the proposed telemonitoring system has been tested with a mechanical ventilator typically used in Home Mechanical Ventilation; a home ventilator V supplies a simulated load TL (adult test lung) by means of a pneumatic circuit PC with a mono-tube connection. The air flow sensor has been

Published in order to measure the air flow rate supplied by ventilator to the test lung TL before the exhalation port EP. which is placed in the mono-tube breathing circuit. The pressure sensor has been arranged in order to measure pressure at the delivery port of the ventilator; finally, the thermometer LM35 may be used to measure the temperature of the air supplied by the ventilator, V. The DAQ and the sensors have been enclosed into a plastic housing, MV. Measurement data coming from the pressure and flow sensor are acquired by means of the data acquisition card DAQ (sampling frequency of 20 Hz) that subsequently sends them to a laptop PC (Figure 8). Data is then processed and sent to a server farm and remote workstations by means of an Internet connection, so that the temporal pattern of measured data are available to remote devices (e.g. smartphones and laptops, Figure 9) used by physicians, nurses and caregivers, before a password authentication protocol (PAP). Measurement data acquired during an experimental trial are in accordance with the settings of the home ventilator (i.e. ventilation mode: pressure control; IPAP: 19 cmH₂O; EPAP: 4 cmH₂O; breathing frequency: 14 bpm) and are reported in Figure 8. However, the sampled data for the temporal pattern of air pressure and flow can be processed in order to obtain other vital parameters related to ventilation frequency. mechanical (e.g. breathing inspiration time, tidal volume, minute volume, peak flow, mean pressure, IPAP and EPAP)²¹⁻²². Temporal patterns of air differential pressure and flow rate are provided to remote devices (Figure 9) used by physician, nurses and caregivers, allowing for continuous and real-time telemonitoring both during a single breath and for every breath occurring during the whole day. Moreover, beyond the temporal patterns of air flow rate and differential pressure, current values of IPAP, EPAP and breathing frequency are provided both on the screen of laptop of the Patient Ventilation Monitoring Unit and on remote devices (Figure 9). Finally, the trend of ventilation parameters (e.g. IPAP, EPAP and breathing frequency) are made available to physicians in order to synthetically summarize monitored data from minutes to several hours (Figure 10). In fact, as reported in Figure 10, the data trend of IPAP, EPAP and breathing frequency may be used in order to evaluate a patient's physical condition and to detect various kind of clinical events (e.g. sleep apnea events and events of a patient's tube disconnection), so that an adequate and appropriate action may be carried out, and the event may be stored in a list of alarm events. As example, Figure 10 shows the data trend of IPAP, EPAP and breathing frequency for a monitoring period with a duration of more than 4 hours; the detection of such clinical events is reported in the following section.

Data trends of IPAP and EPAP are useful to evaluate if any disconnection of the breathing circuit has occurred and it is possible to reveal this kind of event by means of a drop detection of both IPAP and EPAP values. During experimental trials carried out with the setup shown in Figure 7 for a duration of about four and a half hours, the breathing circuit supplying a test lung was disconnected from the ventilator twice and reconnected after some seconds; in the Figure 10(a), these two events of tube disconnection are detectable by observing the two pressure drops occurring at about the 3000th and 10000th second from the beginning of the monitoring period.

B. Detection of apnea events and breathing frequency variations

Data trends of breathing frequency may useful to evaluate if any sleep apnea event has occurred and it is possible to reveal this kind of event by means of a reduction in the value of frequency. During an experimental trial carried out with the setup shown in Figure 7, two sleep apnea events have been simulated by changing the setting of breathing frequency on the pulmonary ventilator. In Figure 10(b), these two events are detectable by observing the reduction of frequency value occurring at about the 4000th and 12000th second from the beginning of the monitoring period. These data are useful to count the number of sleep apnea events per hour, which is an important parameter in the clinical evaluation of obstructive sleep apnea

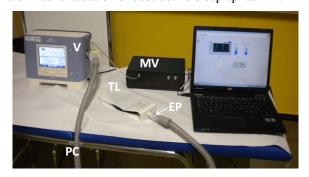


FIG. 7. Experimental setup for trials with a home mechanical ventilator with mono-tube connection, V: mechanical ventilator; TL: (adult) test lung; MV: housing for sensors and data acquisition system; EP: exhalation port: PC: patient circuit. (Flow sensor not shown).

A. Detection of events of tube disconnection

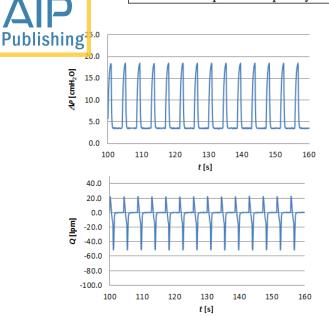


FIG. 8. Experimental results during an experimental trial with a pulmonary ventilator typically used during home mechanical ventilation. From the upper plot, temporal pattern of differential pressure and air flow rate. Duration of about 1 minute.

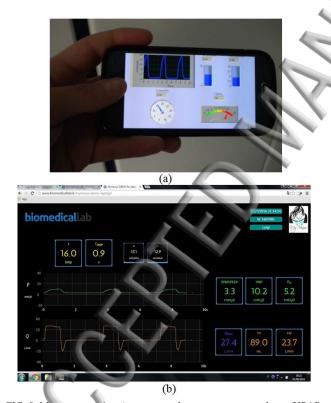


FIG. 9. Measurement data (e.g. temporal patterns, current values of IPAP, EPAP, mean pressure, breathing frequency, inspiration time, tidal volume, minute volume, peak flow, resistance and compliance) available on remote devices. (a) User interface shown on smartphone. (b) User interface shown on a webpage by means of a laptop.

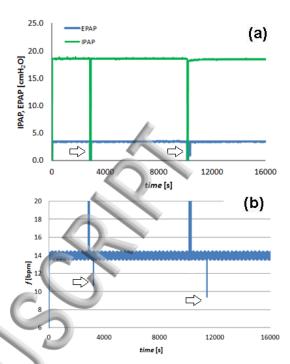


FIG. 10. Data trend of (a) IPAP and EPAP, (b) breathing frequency. Arrows shown events of tube disconnection in (a) and sleep apnea events in (b).

DISCUSSION AND CONCLUSIONS

Patients who have acute respiratory failure and who have not responded to other treatment options can benefit from using Home Mechanical Ventilation. In order to allow for remote patient monitoring, in the last few years, several tele-monitoring system for home mechanical ventilation have been proposed. However, they usually are not realtime devices and do not provide continuous monitoring of a patient's physical condition; in fact, they monitor only some breaths during all day (sample monitoring), while breathing condition may vary very significantly during the day and from one breath to another. Furthermore, for a single breath, the above quoted devices usually only provide the ventilated volume or peak flow, and the maximum and minimum pressure value, but they do not make available the temporal pattern of the air flow rate or differential pressure during a single breath. In order to address these issues the development of a novel remote monitoring system for long-term home-based ventilation therapy is reported, in this work, together with two configurations of the ventilation monitoring unit placed at the patient's home. With the both configurations (wired and wireless), it is possible to monitor each patient breath with a frequency of 20 Hz, suitable for the application of pulmonary ventilation⁷, allowing remote and continuous monitoring of every breath during the entire day and of the dynamic trend of each single breath occurring during the day²¹⁻²². In particular, all measurement data are provided to a Data Base Management System and made available to remote devices (PCs, tablets or smartphones) used by

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Publishings, nurses and caregivers by means of TCP/IP transmission protocol. Moreover, the proposed device provides a data trend which can be used in order to detect various kind of clinical events (e.g. sleep apnea events and events of patient's tube disconnection). The developed RPM system allows observation of different remote therapy units everywhere located in different places of a city, region or country and has been successfully tested by means of experimental tests carried out with pulmonary ventilators typically used to support sick patients (both with mono-tube and bi-tube breathing circuits).

Other configurations will be developed in order to improve the performance of the system and the encryption method. The signal processing might be also used in order to detect any alarm conditions; for example, for each medical parameter, a range of acceptable values can be remotely set by means of the workstations used by physicians. If the value of the (directly or indirectly) measured parameters falls outside the set range, an alarm may alert individuals monitoring workstations (i.e. members of medical staff, caregivers and family members), so that an adequate and appropriate action may be taken, and the event may be stored in a list of alarm events. Other future developments include performing clinical trials in order to perform a clinical evaluation of the proposed device.

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