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Mechanical Ventilator Spontaneous Breathing Detection Tested by Robot SIMVENT

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***Abstract*—Mechanical Ventilators (MV) are only tested at the manufacturer's facilities in their ability to detect spontaneous breathing so as to trigger concomitant support. A robot patient was developed (called SIMVENT) to test MVs after repair or to compare MVs in hospitals. SIMVENT is a complete active patient simulator, as opposed to rubber bag simulation. SIMVENT implements lung equations under given user selected parameters of ventilatory mechanics to simulate different respiratory conditions. By producing spontaneous breathing (SB) pressure drops (1-10 cm H2O) at random times or phase-locked to ventilation cycles, SIMVENT tests the capacity of MVs to sense spontaneous ventilation. SIMVENT also calculates basic mechanical parameters (frequency, airway pressure, esophageal pressure, resistance and compliance). SIMVENT was designed with a step-motor powered piston moving in a 2-litre cylinder, a second cylinder mimicking residual volume, pressure sensors, a variable resistance tube, a microcontroller and a computer interface. A normalized spontaneous breathing detection graph was constructed for two MVs: one behaved well and the other could be harmful if ventilating a patient during weaning, because SBs were not sensed at the set pressure-drop value.**

***Keywords*—mechanical ventilator, simulator, spontaneous breathing**

I. Introduction

Modern Mechanical Ventilators (MVs) perform complete self tests and calibrations in order to ensure reliable operation at power-on and before they are used to ventilate patients. While no reports of malfunctioning are published, it would be desirable to have external test platforms to compare different MVs or to record all tests passed by a particular MV to be included in its technical usage documentation. Manufacturers of MVs offer a passive patient simulator used for demonstrations, giving the user the possibility to select two basic mechanical parameters, total airway resistance (R) and chest compliance (C). The remaining behavior of the test is commanded from the MV, driving the passive patient simulator. The market has also seen the recent introduction of an active simulator [1], at the same dates SIMVENT was designed and first published [2,3]. Another academic research has produced and published a patient simulator for continuous mechanical simulation [4]. The patient simulator described here, SIMVENT, was designed so as to calculate at all times the simulated lung volume as a function of internal pressure measurement and set compliance, according to the basic ventilation equation modeled [5]. While the use of SIMVENT to simulate respiratory mechanics of a ventilated patient and therefore to check the parameters measured by a MV in terms of respiratory frequency, tidal volume and pressures is shown elsewhere [3], we report here the ability of robot SIMVENT to check the spontaneous breathing detection capacity of MVs.

II. Design of Robot SIMVENT

A comprehensive robot was designed and built [3]. Figure 1 shows the main components which include air tubes, step motors and a microprocessor to interface the mechanical behavior to SIMVENT software running on a computer (not shown).

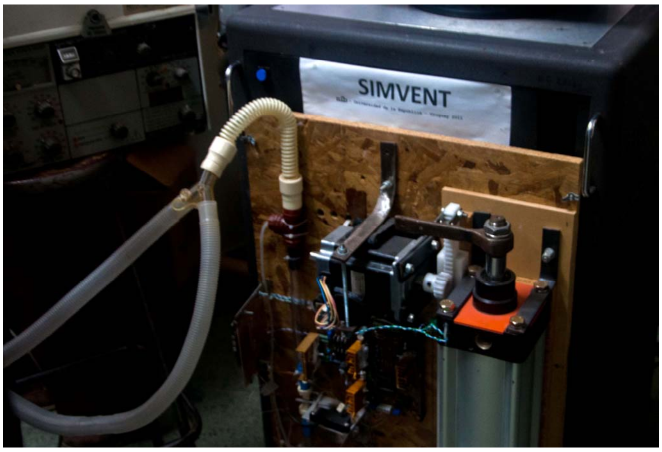

Fig. 1. SIMVENT robot. Note the "Y" tube, which is used to connect to a Mechanical Ventilator (MV). The piston in the cylinder defines the lung volume according to lung equations. (With permission from Simini et al.[7]).

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Lung volume is given by the position of a piston in a cylinder. The mechanical system consists of a pneumatic cylinder with a rod, a stepper motor, pressure sensors and an encoder (Figure 1). SIMVENT is based on feedback taken from a pressure sensor inside the cylinder. Knowing the position of the encoder "lung" volume is known.

Combining internal pressure of the cylinder with compliance (which is a simulation parameter) the volume value is obtained at all time tics, and the shaft is moved accordingly. If the measured volume is different from the volume value obtained from the mathematical relationship, then the step motor moves the piston, changing the "lung" volume of the cylinder. The device is therefore capable of varying its volume according to the pressure and prior volume.

In addition to continuous simulation, SIMVENT is capable of generating short bursts of negative pressure super-imposed on the normal ventilation simulation to exhibit the spontaneous activity a patient has prior to weaning. A sign of approaching ventilatory independence, the spontaneous breathing (SB) of a patient is an event to be detected in order to avoid side effects such as barotrauma.

III. Testing of Ventilators

A. *Testing Methodology*

First, a MV is connected to SIMVENT, whose behavior (R and C) is imposed by a software application connected to the microprocessor by USB [7]. Second, set the MV parameters, including the sensing "sensibility" to SB in terms of pressure drop and tolerance. Third, give SIMVENT the SB orders as pressure drop and its time occurrence at random over the respiratory cycle. Fourth, start the simulation acquiring signals in computer files. A comparison of the SB created by SIMVENT and the resulting change in pressure signal commanded by the MV was manually performed for 20 cycles for each SB pressure drop value (1 cm H2O, 2 cm H2O, up to 10 cm H2O). The percentage of correct SB detection was graphed in the ordinates while the abscissa was given the "sensibility" set on the MV in terms of % of the centre value. Both parameters were normalized to use the same graph for all 10 SP values (1 cm, 2 cm, etc.)

B. *Mechanical Ventilators Tested*

Four MVs were tested in our Laboratory at the University Hospital. One was from the PhysioPathology Department, two were borrowed from a local vendor and the fourth was the Intensive Care redundant MV. For the present study two of these MVs were used, drawn at random.

IV. Results

Figure 2 and Figure 3 graphically show the results of a MV behaving in the way it is expected and another MV probably uncalibrated or clearly wanting service.

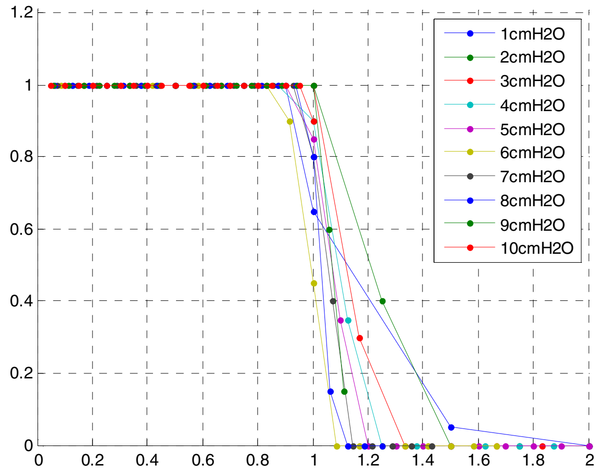

Fig. 2. Detection Rate (y-axis) vs Normalized Pressure Drops [Real/Nominal] (x-axis) of a good Mechanical Ventilator (MV). Nominal pressure drop sensibility form 1 cm H2O up to 10 cm H2O were tested. For real pressure drops that are higher than the nominal threshold set on the MV, detection of spontaneous breaths (SB) by the MV is almost always correct. For real pressure drops that are lower than the set threshold, this MV correctly detects SBs but over-reacts (up to 40% of SBs developing a pressure drop that is about 25% below the set threshold -i.e. 1.25 on the x-axis-) for a set sensibility of 9 cm H2O. Overall, this MV detects SBs in good agreement with SIMVENT from 1 to 10 cm H2O.

The behavior of the MV in Figure 2 shows good agreement with expected SB detection, irrespective of SB normalized amplitude (from 1cm to 10 cm H2O), with normal sensibility set on the MV. As the sensibility gets more demanding the percentage of detection of SB decreases towards zero when robot SIMVENT generated pulses which differ increasingly from the nominal value (which is correct).

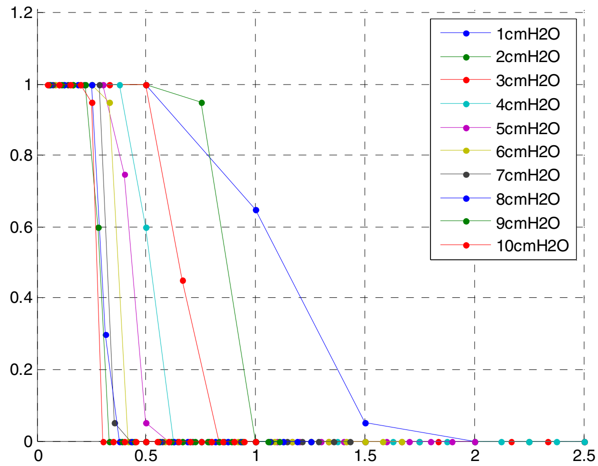

Fig. 3. Detection Rate (y-axis) vs Normalized Pressure Drops [Real/Nominal] (x-axis) of an uncalibrated Mechanical Ventilator (MV). Nominal pressure drop sensibility form 1 cm H2O up to 10 cm H2O were tested. For real pressure drops that are higher than about TWICE the nominal threshold set on the MV (i.e. 0.5 on the x-axis), detection of spontaneous breaths (SB) by the MV is almost roughly correct. Overall, this MV was diagnosed by robot SIMVENT as not reliable for clinical use, for all pressure drop thresholds, except for 1 cm H2O with 65% detection rate for nominal value pressure drop. For all other settings, this MV reacts only if SBs of at least TWICE the set amplitude are produced by SIMVENT.

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By contrast, the behavior of the MV described in Figure 3 is different, because SBs are hardly detected at the set values. SBs are detected only if their real pressure drop is at least twice the set threshold (50% on the x-axis), below which SBs are ignored by the MV. The conclusion is that this MV should not be used clinically.

V. Discussion

By submitting our robot SIMVENT to be ventilated by MVs a new test methodology is now available. In addition to existing external tests regarding calibration of mechanical parameters such as frequency, pressure or airflow, SIMVENT is capable of creating SBs to be detected by the MV under test.

The MV of Figure 2, when normalizing its behavior to let all pulse amplitudes to be comparable, exhibits a normal pattern, giving Service personnel and Clinical staff confidence to use the instrument. On the other hand, the MV of Figure 3 ignores SBs created by SIMVENT and that should trigger ventilator reaction to follow the patient breathing. This shows that its use could be harmful, because the MV does not behave in the way the clinician set it to operate, i.e. react with 3 cm H2O drops.

With the present demonstration that robot SIMVENT can distinguish reliable from non reliable MVs, a future enhancements will be to include the generation of a standardized report of MVs, with respect to SB detection at different nominal pressure drop settings. The interpretation of the calculated reliability figures will be similar to a "diagnostic sensibility" usually depicted in a ROC curve (Receiver Operating Characteristic). The equivalent of "diagnostic specificity", which is necessary to draw a ROC curve, will also be calculated during the SIMVENT test, because we have observed that noise in the pressure signal may trigger SB detection, when the sensing parameters of the MV are set very low.

The present development stage of SIMVENT is such that one may envision new functions and uses for the instrument. Initially a simple robot was designed to oppose the equations of human mechanical ventilation to a MV under test (with no patients involved). Now the addition of SB capability gives robot SIMVENT a new function and usefulness, that of distinguishing reliable MVs from MV to be serviced or substituted.

VI. Further work and Conclusions

Consider now the robot patient (i.e. SIMVENT) to be a state machine with an internal state defined by parameters R and C (airway resistance and compliance) and by hidden variables of Oxygen concentration in arterial blood (PaO2) and Carbon Dioxide concentration in arterial blood (PaCO2), keeping track of oxygen and carbon dioxide in blood. The hidden variables can be calculated at all time intervals from the previous value and a function of airflow, specific air pressures, tidal volume and respiratory frequency. Some of these parameters are set by the user onto the MV, while others are calculated, giving way to a possible full hybrid simulator. The user will interact then with (a) software, (b) hardware patient simulator SIMVENT and (c) real MV connected to the robot SIMVENT. The "real life" feeling of such a simulator would far exceed the usual software simulators available.

A hybrid simulator SIMVENT could be used for training, as the student will be able to observe the consequences of restricting ventilation on a robot patient or what happens if much higher frequency and tidal volume are imposed on an already highly oxygenated robot patient. Other teaching simulators [8] have partially addressed our goal for future work. Giving realistic behavior to SIMVENT is a pending goal of the present research, a goal the teaching community endorses.

Another goal to tackle for SIMVENT to be the reliable assistant all clinician and servicemen whish to have by their side, is to create an output document compatible with Electronic Health Record (EHR), which are progressively leaving paper to become electronic. The Clinical Document Architecture (CDA) is the standard, related to larger Health standards, such as the Hl7.

By designing the output of SIMVENT as a regular clinical information system, with the same protection against non authorized use of medical data and the same availability across the health continuum, MV testing data will be available at the clinicians request in an understandable format, and even linked to patient clinical data, adding traceable quality control to health records of ventilated patients.

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