SIMVENT – Patient Simulator to Test Mechanical Ventilators

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Abstract—**Background: Patient simulators for ventilators are usually passive devices consisting of rubber balloons, springs and tubes. In all but one simulators reviewed the ventilator under test (VUT) provides energy: simulation is limited to passive resistance/compliance with no sham spontaneous breathing to trigger the mechanical ventilator (MV).**

Objective: We improved our SIMVENT, a simulator to materialize lung equations with user selected ventilatory mechanics parameters, capable of producing spontaneous breathing to test MV operation. SIMVENT evaluates ventilators as VUTs. We designed an assisted ventilation training software to operate SIMVENT.

Method: SIMVENT includes a cylinder with a step-motor powered piston, a cylinder mimicking residual volume, sensors for “alveolar” & “airway” pressures, a step-motor compressed tubing to simulate variable airway resistance, a microcontroller and a computer interface. SIMVENT acts as a patient with programmed values of airway resistance and lung compliance. SIMVENT compares flow and pressure signals with those shown by the VUT. Spontaneous inspiration attempts are created by SIMVENT to test VUT: breathing pressure drops are selected (5 cmH2O e.g.) either at random or phase-locked to the respiratory cycle. A report is generated for each VUT. SIMVENT was designed with "User centered" methodology.

Results: Four ventilators were tested. VUT tidal volume differed up to 15%, airway pressure was within 8% and respiratory frequency within 4% of SIMVENT values.

Conclusions: SIMVENT proved to be useful to test and compare ventilators as to their ability to detect spontaneous breathing. For the first time ventilators can be fully evaluated prior to clinical use. SIMVENT may also be used to train physicians.

Keywords— **mechanical ventilator, simulator, training.**

Introduction

Mechanical ventilation in case of respiratory failure is tailored to the needs of each specific patient. The equipment has to be reliable and is expected to follow any breathing attempts by the patient so as to support or take command on his/her respiratory cycle. Before going into clinical use, VMs must be tested. Patient simulators are usually passive devices consisting of rubber balloons, weights and tubing. While mechanical parameters (resistance and compliance) can be tested with passive simulators, such devices are of no help to test the ability of a MV to detect any patient spontaneous inspiration. Only recently has an active lung simulator been offered commercially [9], which is a confirmation of the need of better MV testing.

Present practice is that clinical use of repaired or new models of MV are put in use with no familiarization with the equipment, nor mock use to test. This is a characteristic of MV, as opposed to other Biomedical Equipment associated with test benches (ECG, imaging phantoms, electro surgery units).

The observation that MV training in clinical setting has no prior instances but theory and observation of experienced colleagues, led to the conclusion that a patient simulator would be welcome. To answer these needs -an objective instrument to test MVs and to be safely ventilated by beginners- we set ourselves the goal to develop an active "lung simulator" which would behave as a variety of possible ventilatory pathologies by varying its parameters to simulate patients with different characteristics and respiratory diseases.

The original simulator [1] is the result of an inter-disciplinary joint research of the Núcleo de Ingeniería Biomédica (**nib**), the Department of Pathophysiology and the Pulmonary Function test Laboratory, School of Medicine, University Hospital, Universidad de la República. The results of a redesign and the addition of training characteristics to SIMVENT are reported here.

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THEORETICAL BACKGROUND

A. Mechanical ventilators

Ventilatory mechanics describes the movement of air into the respiratory system going in and out. The air comes from medical gas sources and is directed towards the inside of the alveoli. For this to happen respiratory muscles perform the effort required to lower lung pressure below atmospheric pressure and thus achieve an airflow into the chest: this is called inspiration. Air inflow must overcome thoracopulmonary viscoelastic forces and airway resistance. During expiration the air is forced out as a result of the relaxation of involved muscles. The airway resistance is due to air friction against the inner walls of the bronchi and around the pulmonary tree.

A ventilator is a device capable of supplying the patient's ventilation control to enable gas exchange. A mechanical ventilator (MV) is needed when the patient cannot overcome the increased mechanical load (friction forces) imposed by the pathology. MVs thus perform or support the patient's ventilatory function.

Ventilators can be separated into two broad categories, negative pressure ventilators and positive pressure ventilators. Positive pressure ventilators are devices that pump air at pressures above atmospheric pressure, enabling inspiration through a tube connected to the patient's airway. To achieve the expiratory phase, the device connects the patient airway to atmospheric pressure which causes the air to be expelled. The SIMVENT simulator is designed to test this type of MVs: positive pressure ventilators.

B. Basic diagram

Within a MV, the control system interacts with all other parts (Fig. 1) and is responsible for processing information received by sensors, for alarm handling in case of anomalous behavior, for receiving user commands to be transformed into actions. Control system also decides if it is necessary to back up or to turn into emergency ventilation, among other functions. Power comes from either the mains or from rechargeable batteries.

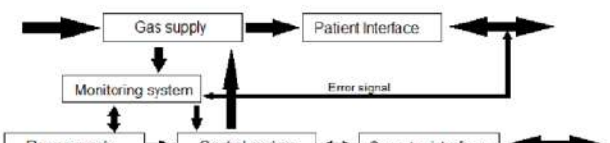

Fig. 1 - Block diagram of a Mechanical Ventilator.

MVs generally use two gas inputs, air and oxygen. These inputs are pressurized at between 2 to 5 bar. The combination of oxygen and air takes place in a device called "blender". It is possible to deliver oxygen concentrations from 23% (normal air) up to 100%.

The Monitoring system is responsible for keeping all relevant parameters within set limits in order to insure a good patient ventilation. It provides data to the control system to achieve the goal set by the user and to detect anomalous events that may affect the patient. The monitored parameters are air flow, tidal volume and airway pressure. Other parameters are also monitored depending on the particular MV, such as air temperature, gas supply pressure or oxygen concentration.

The operator interface is the part responsible for communication between the user and the ventilator control. The user sets the parameters of the desired ventilation: respiratory frequency (f), inspiratory time (Ti), ratio of inspiratory to expiratory time (I:E), tidal volume (Vc), maximum pressure (Pmax), positive end expiratory pressure (PEEP) and trigger pressure. The screen displays pressure, flow and volume curves versus time. It is possible to set alarm levels. Users also select the operation mode in which the ventilator will perform.

C. Lung System model

The basic lung model consists of a resistance to airflow and lung compliance in series. The simplest model has it that both air resistance and compliance remain constant for any value of flow. SIMVENT adds to the basic model a piecewise linear compliance, i.e. a different linearity according to air flow. SIMVENT sets airway resistance as constant irrespective of flow.

Resistance to airflow

In the respiratory system, the gas flow that goes in or out during breathing must overcome forces that oppose it. Airway resistance is defined as the relation between the applied pressure difference and the air flow.

Compliance

Compliance is the elastic capacity of the respiratory system to oppose anatomical structure deformations. It is estimated as the volume change produced by a variation in pressure.

SIMVENT IMPLEMENTATION

D. Hardware

SIMVENT is a device operating according to the lung equations of the simple model adopted. Simulated lung volume is given as a function of internal pressure and current compliance. To achieve the calculated lung volume, SIMVENT adjusts 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 to track the piston position (Fig. 2). SIMVENT uses pressure feedback from inside the cylinder to move the piston to set a "lung" volume according to the equations.

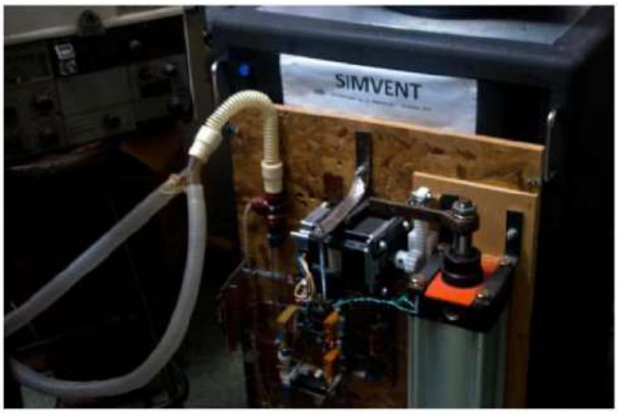

Fig. 2 - Implementation of a second SIMVENT prototype. Note the "Y" tube which is used to connect to Mechanical Ventilators (MV)

Combining the internal pressure of the cylinder with the 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. At all time tics, SIMVENT is therefore capable of varying its volume according to the current pressure and prior volume.

E. SIMVENT software to simulate a patient

SIMVENT operates to test a MV when connected as shown in Fig. 3. The Test software sets patient parametres to SIMVENT while the operator manually commands the MV. Ventilation takes place during which the software receives pressure, flow and tidal volume curves from SIMVENT robot. Respiratory frequency and mechanical parameters measured by the MV are compared to the original "patient" settings loaded into SIMVENT. A report of the test session is created and all signals can be saved as files for off line processing.

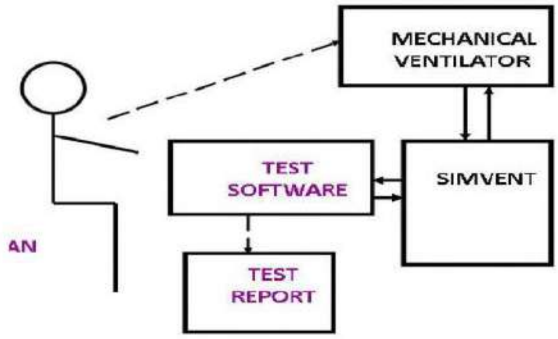

Fig. 3 - SIMVENT as a robot-patient ventilated by a Mechanical Ventilator being tested. MV measured parameters are manually entered into the Test Software to compare them to original SIMVENT settings.

F. SIMVENT Software to train students

SIMVENT-DOCEO is a software which allows to command SIMVENT hardware as a robot-patient being ventilated (Fig 4). SIVENT-DOCEO performs:

- Setting of compliance and resistance of a patient according to a physio-pathological condition
- Definition of time compression to shorten simulations
- MV settings manual entry
- Local area network (LAN) connection to some MV models for dta interchange.
- Real time pressure, tidal volume and flow graphs
- Display of the "physiological operating point" in terms of two variables in an x-y plane.
- Report of teaching sessions with results in terms of "clinical success" or failure.

VENTILATOR TEST RESULT

SIMVENT was used to test the operation of four mechanical ventilators, both recent and vintage: Intermed Inter7, Neumovent Graphnet, Maquet Servoi and Siemens Servo 900D. Results of the accuracy of the MVs are given elsewhere [1, 2]. Tidal volume of MVs differed up to 15%, airway pressure was within 8% and respiratory frequency within 4% of SIMVENT values.

TRAINING WITH SIMVENT

SIMVENT and SIMVENT-DOCEO may be used to train students (Fig. 4) with "stiff lungs" disease, Chronic Obstructive Pulmonary Disease (COPD) conditions and other combinations of resistance and compliance. Instructors will be able to offer their students a variety of conditions, not easily seen during short hospital stays of Medical School. Other health related technicians will also be able to experience MV dynamics.

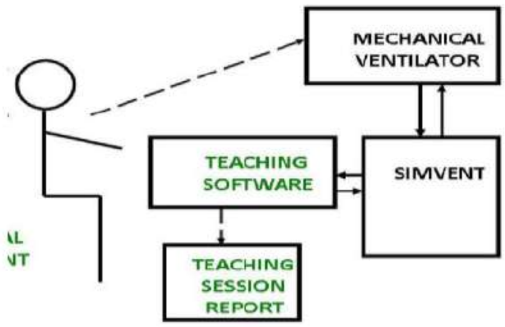

Fig. 4 - SIMVENT as a robot-patient ventilated by a student.

DISCUSSION AND CONCLUSIONS

We have enhanced an existing simulator designed to test VM [1]: a smaller footprint, better communications and the addition of a new software application to use the robot-patient for training, called SIMVENT-DOCEO. The availability of test tools to verify Biomedical Equipment is a must in present day scenarios of Total Quality paradigm. With SIMVENT MVs will be submitted to standard checks, comparing robot lung parameters with the measured values. The same hardware, SIMVENT, used both to train students and to check MVs strengthens the reliability of the instrument. With the new application, SIMVENT-DOCEO, students and clinicians make their hand ventilating all sorts of respiratory conditions in real time or faster time, with no real patients around.

As SIMVENT accumulates operating hours, new ideas are suggested by users and developers, such as smaller size, compatibility with other operating systems, including portables, tablets and web based applications.

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