MICROCOMPUTERIZED SYSTEM TO ASSESS THE PERFORMANCE OF LUNG VENTILATORS

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Abstract: Lung ventilators may harm patients if they are not properly calibrated. Therefore, they must be periodically assessed to verify if the supplied volume and pressure match the ventilatory settings. This paper presents a system based on a microcomputer to assess the performance of lung ventilators. The hardware of the developed system contains three modules: transducer, conditioning and acquisition. The transducer module converts, to electrical signals, the pressure and flow waveforms supplied to a lung simulator by a lung ventilator. It also supplies digital measurements of temperature and relative humidity (RH). The conditioning module amplifies and filters the pressure and flow signals. The acquisition module reads the digital measurements (temperature and RH) and carries out the analog to digital conversion of the conditioning module outputs, sending these data to the microcomputer via radio-frequency. Software written in C++ shows the acquired waveforms on the PC screen and calculates the parameters required by the IEC 60601-2-12. Data on the lung ventilator model, the sampled waveforms and the calculated parameters are stored in a database, allowing the equipment follow-up. Comparative result of tests carried out with the developed system and with commercial equipment is presented.

1 INTRODUCTION

Lung ventilators (LVs) supply air to patients that are unable to breathe spontaneously, for instance, due to chronic obstructive pulmonary disease, acute lung injury, anesthesia or neurological disorder. Therefore, they are widely used in intensive therapy units (Pierce, 1995).

The LVs are built according to the IEC 60601-2-12 that establishes the requirements needed to minimize patients and operator risks (International Electrotechnical Commission, 2001).

Since the LVs are used in critical clinical situations, they must be periodically assessed to verify if their performances were not degraded over time, that is, if the supplied values match the ventilatory settings on the LV. Besides, lungs may be harmed by high airway pressure and high tidal volume (Ricard et al., 2003; Wrigge et al., 2004; Fernández-Pérez et al., 2006).

Therefore, it is very important to implement a quality control program for LVs in order to avoid patient injury.

Nevertheless, quality control programs in developing countries are hampered by the high cost of performance analyzers. Very often, heavy taxes make the importation of these analyzers prohibitive, preventing proper maintenance.

This work describes a lower cost LV analyzer based on a PC microcomputer. It consists of an electronic device to sample pressure, flow, temperature and humidity. The sampled data are sent, via radio-frequency, to a computer where the waveforms are shown in real time. Parameters to

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evaluate the LV are calculated. All data are stored in a database.

2 MATERIALS AND METHODS

The Figure 1 depicts a block diagram of the developed system and shows how it is connected to the LV and lung simulator (LS). The LS acts as a physiological load (resistance and compliance) for the LV under assessment.
The developed system consists of an electronic device that periodically measures the temperature and relative humidity (RH) of the air inside the duct that connects the LV to the LS as well as the flow and the pressure waveforms generated by the LV. The acquired data are sent to a PC microcomputer via radio frequency (RF). The PC shows the sampled data on the screen as well as parameters required by the IEC 60601-2-12.

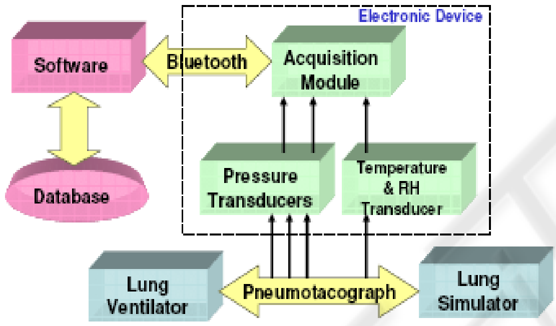


Figure 1: Block diagram of the system developed to assess LV performance. It also shows how the system is connected to the LV and LS.

The next sections describe each block of the developed system.

2.1 Transducer Module

The transducer used to measure temperature and relative humidity (RH) is the SHT75 (Sensirion Inc, 2007). It measures temperature from -40 to 123.8°C (accuracy: ±0.5°C; resolution: 0.01°C) and RH from 0 to 100%RH (accuracy: ±1.8%RH; resolution: 0.03%RH). These transducers have a calibration certificate issued by the manufacturer.

Due to its small size (0.42 x 4.88 x 2.5 mm), it is possible to insert the transducer into the air duct that connects the LV to the LS.

The SHT75 yields the measurements in digital format (14 bits) via a 2-wire protocol. This is a bidirectional protocol that allows the sensor to receive data such as commands to carry out the measurements.

Before connecting the LV to the LS, the sensor is exposed to the environment, allowing the system to register the local temperature and RH.

To sample the flow and pressure produced by the LV, two DC030NDC4 pressure transducers are used (Honeywell Inc., 2008). The DC030NDC4 measures the differential pressure applied to its inputs in a range of ±76.2cmH_2O. It has a sensitivity of 52.36mV/cmH_2O, producing a voltage output of 2.25V ± 2.0V.

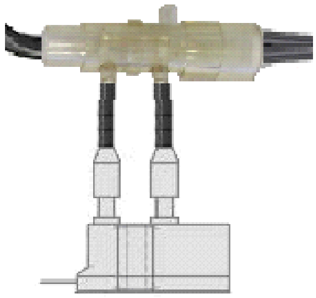
An acrylic apparatus containing an obstacle is placed between the LV and LS to create resistance to the gas flow (pneumotacograph - PT). The pressure drop across the resistance, measured by one of the transducers, is proportional to the flow velocity (Doeblin, 1990). The Figure 2 shows how the transducer inputs are connected to the PT apertures as well as a front view of the flow resistance. The pressure drop is positive for inspiratory flow and negative for expiratory flow.

To relate the A/D converter voltage input (that is, the amplified and filtered differential pressure transducer voltage output) to flow, 40 different flow rates (20 positive and 20 negative) were applied to the PT and to a calibrated flow meter (Fluke Biomedical VT-Plus; uncertainty of ±1,1l/min for the -70 to +70l/min range). They were connected in series to allow the comparison of their measurements. An illustration of the experimental setup is shown in Figure 3. A polynomial of seventh order was fitted to the experimental points (voltage input versus flow rate measured by the calibrated meter) to allow inferring measures for flow rates not evaluated. Using the polynomial, the flow measurements obtained with the developed system have an uncertainty of ±4.4l/min.

The second transducer, connected to a third aperture of the acrylic device, measures the difference between the atmospheric pressure and the one within the air duct.

To calibrate this transducer, 35 pressure values (from 0 to 37.1cmH_2O) were applied to the transducer and, in parallel, to a calibrated meter (Fluke Biomedical BP-Pump 2; uncertainty: ±0.2cmH_2O for a range from 0 to 120cmH_2O). The conditioned voltage output of the transducer (as supplied to an A/D input) and the pressure readings obtained from the calibrated meter were annotated.

From these values, a first order polynomial between voltage and pressure was obtained.



(a)

(b)

Figure 2: Diagram that shows how the pressure transducer is connected to sample the flow waveform (a). Below (b), there is a front view of the air resistance that provides a pressure drop proportional to the flow velocity.

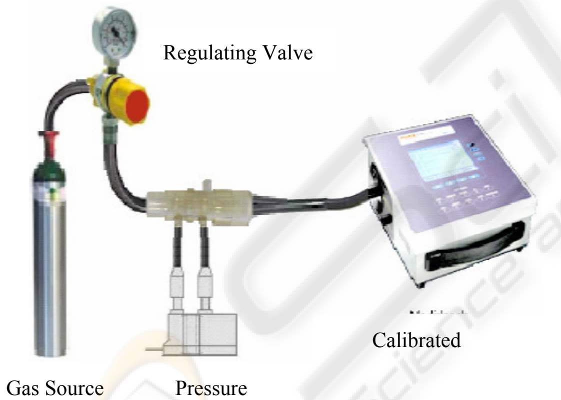


Figure 3: Experimental setup to calibrate the flow measurements obtained with the developed system.

2.2 Conditioning Module

The electrical outputs of the pressure transducers require further processing before being sampled. Both signals are applied to second order Butterworth low pass filters that have cut-off frequencies of 40Hz. For the expected ranges (pressure: 0 to 40cmH_2O; flow: −70 to +70l/min), the output amplitudes are adjusted to the input range of the acquisition module (0 to 2.5V). For that, they are amplified and shifted to positive values. The achieved resolution is 50.0mV·(cmH_2O)$^{-1}$ for the pressure and 17.9mV·(l/min)$^{-1}$ for the flow.

2.3 Acquisition Module

A microcontroller (ADuC841, Analog Devices, 2003) samples the flow, pressure, temperature and RH. The ADuC841 is an optimized single-cycle 20 MHz 8052 core that has an 8-channel analog input multiplexer that feeds a 420 kSPS 12-bit ADC.

In this development, the ADuC841 timer is programmed to sample the flow and pressure waveforms at 160SPS.

For each set of 480 flow and pressure samples acquired (3s), the microcontroller gets measurements of temperature and RH from the SHT75.

Since cables could cause difficulties for the equipment handling, the sampled data are sent to the computer via RF. For that, Bluetooth protocol was chosen since it operates on the ISM band and does not produce interferences in medical equipment (Jones and Conway, 2005; Wallin and Wajntraub, 2004). The Bluetooth module employed is the KC-21 (KCwirefree, 2007), configured for a 115.2kbps transmission rate. The ADuC841 communicates with the KC-21 via its serial interface. A transceiver (SN74LVC1T45, Texas Instruments) was used to convert the ADuC841 TTL levels to the low voltage logic (3.3V) used in the KC-21 bus.

2.4 PC Software

The software, developed in C++ for Windows®, receives data from the electronic device described above and calculates parameters that are stored in a database.

The communication between the PC and the device is established by means of another Bluetooth module (KC-210) inserted into a USB port (Kcwirefree, 2006).

When the user starts the program, a form is launched to be filled up with data on the LV (manufacturer, serial number, model and others). This form also receives information on the environment under which the test is being performed (temperature, RH, atmospheric pressure, measured power supply) as well as on the qualitative assessment of the equipment (maintenance condition of power cord, switches, alarms and others).

All inserted data is stored into an open source relational database system (PostgreSQL - http://www.postgresql.org/) that has native programming interfaces for C++.

The database implemented has two tables: one to keep the information on the LV assessed and another to store the test data.

Using two tables, different tests carried out with the same LV can be stored on the database without the need of reinserting data for each test performed. By gathering the data on a same database, the operator can promptly identify any performance change since the previous results are available.

After registering the equipment in the database, it is necessary to click on a button to proceed to the next form page where the LV operating settings are typed. This second form also requires information on the range and resolution of the meters available in the LV control panel.

Another button is shown that, when clicked on, sends a command to the acquisition module to start the data sampling.

The software was developed according to the test procedure adopted by this laboratory (Tolotti, 2004). The LV is switched on to work in volume cycled mode during 40 minutes. After that, three set of measurements carried out at intervals of 5 minutes are recorded.

From the received flow waveform, the software computes the volume supplied to the LS. Three curves (pressure, flow and volume) are shown on the screen in real time while temperature and RH measurements are updated at 3s intervals. To accomplish that, the software employs the graphic library Graphics32 that provides fast operations with pixels and graphic primitives (http://www.graphics32.org/).

At the end of each respiratory cycle, the software calculates the following indexes: breathing frequency (BF), inspiratory time (IT), expiratory time (ET), inspiratory/expiratory ratio (IER), peak inspiratory pressure (PIP), positive end-expiratory pressure (PEEP), mean airway pressure (MAP), peak inspiratory flow (PIF), peak expiratory flow (PEF), tidal volume (Vt) and minute volume (Vm).

After 5 minutes, the software automatically records the values of all these parameters into the database and warns the operator by means of a pop-up window. When this occurs, the operator has to read the LV meters and type these measurements to be stored. This procedure is repeated twice at 5 minute intervals.

All these parameters and the three curves (one minute interval) are stored into the database.

The Figure 4 gives an example of the waveforms plotted on the screen as well as the fields filled up with the data on the LV and indexes calculated by the software.

A LV belonging to a public hospital was tested using the developed system and a calibrated commercial analyzer.

The test was carried out according to the procedure proposed by Tolotti (2004). The LV was working in volume-cycled mode (10 breaths/minute; IER: 1:2; PEEP: $4cmH_2O$; Vt: 500ml).

3 RESULTS

Table 1 shows the average of three sets of measurements obtained with developed system (DS) and with a calibrated commercial analyzer (CA). The relative error was calculated using the CA values as reference. Since the flow resistance may affect the results, it was not acceptable to connect the two equipments in series to the LV and LS. Therefore, the measurements were separately carried out with each analyzer.

Table 1: Average of three set of measurements obtained with the developed system (DS) and the commercial analyzer (CA). For the other acronyms, refer to the text.

Indexes	Averaged Measurements (CA)	Averaged Measurements (DS)	Relative Error
BF(min^{-1})	10	10	0.00%
IT(s)	2.023	2.05	1.33%
ET(s)	3.963	3.953	−0.25%
IER	1:1.953	1:1.93	1.19%
PPI (cmH_2O)	27.2	26.957	−0.89%
MAP(cmH_2O)	8.8	8.843	0.50%
PEEP(cmH_2O)	4.03	3.94	−2.23%
PEF(l/min)	48.34	54.89	13.54%
PIF(l/min)	20.61	20.63	0.10%
Vt(ml)	552.53	551.33	−0.22%
Vm(l/min)	5.537	5.517	−0.36%

Figure 4 exemplifies how the measurements and sampled waveforms are obtained.

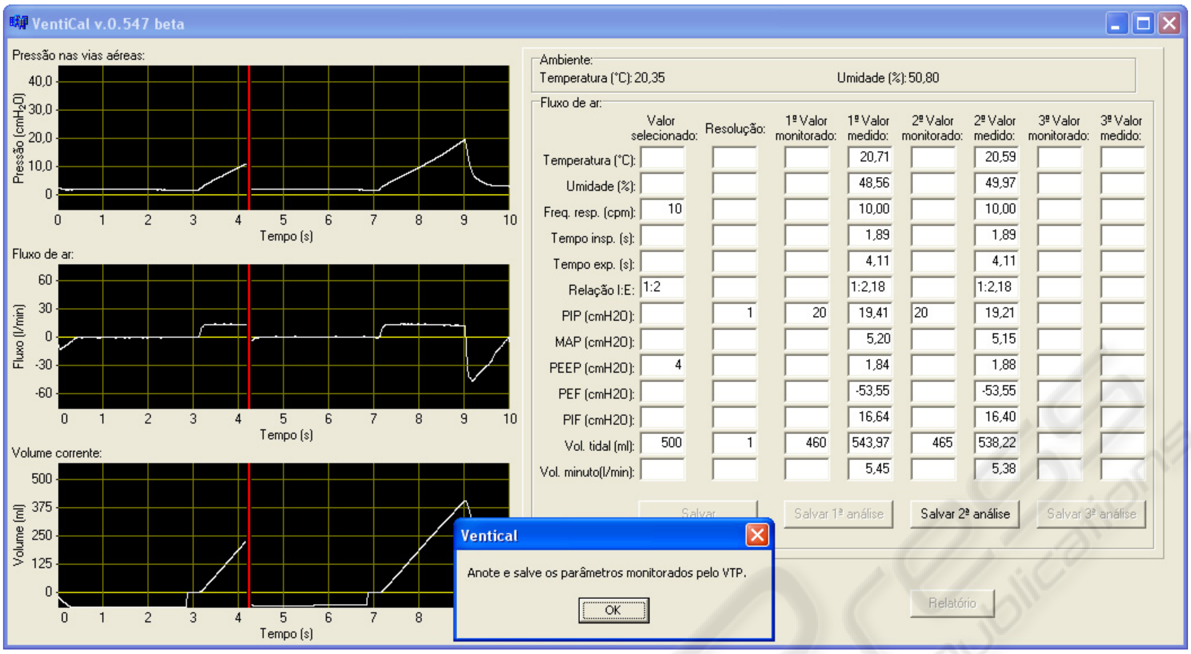


Figure 4: Screen presented by the developed software after performing a second set of measurements. A pop-up window asks to insert the LV meters readings. In the first column, the operator has to inform the LV settings and, in the second one, the resolution of the available LV meters. The fourth, sixth and eighth columns will be automatically filled up by the measured and calculated indexes. Each one is obtained 5 minutes apart from each other. The third, fifth and seventh are filled by the operator with the readings from the available LV meters. The indexes, from the first to last row, are: Temperature, RH, BR(min^{-1}), IE, IT, ET, IER, PIP, MAP, PEEP, PEF, PIF, Vt, Vm. The presented curves from top to bottom are: pressure, flow and volume. The red line is a cursor that shows where the previously acquired waveforms are being overwritten by the new samples.

4 DISCUSSION

Table 1 points out that, except for the PEF value, the developed system has a good performance.

The error for the PEF can be explained by the differences between the mechanical resistances of both systems. During the expiratory phase, the LV just opens a valve to empty the LS without controlling the flow. Therefore, if the analyzers have different flow resistances, they will produce different PEF measurements. It should be mentioned that the IEC 60601-2-12 does not establish a flow resistance value for the analyzers. Therefore, to analyze the LV performance over the time based on this index, a same analyzer model shall be used.

5 CONCLUSIONS

A micro-computerized system to analyze the performance of lung ventilators was successfully implemented.

It has some better characteristics when compared to commercial equipments.

A database is integrated to the analysis software. For each test carried out, it is possible to store the date, sampled waveforms and measurements under the same equipment record. Therefore, it is easy to follow up the LV performance along the time. Besides, the database can provide information on the life expectancy and the average number of repairs for a given LV model, assisting the purchase of new equipments.

RF communication between the acquisition module and microcomputer provides comfort to the operator. The computer can be placed by the LV control panel to facilitate the registration of its meter readings as required by the adopted procedure.

As the equipment interface and indexes calculation are provided by the microcomputer (usually available to the clinical engineering staff), the hardware module has lower design complexity when compared to similar analyzers and, therefore, lower cost.

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