Implementation and Validation of an Integrated System to Measure Parameters of Respiratory Mechanics Aimed at Improving Patient Ventilatory Assistance

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Abstract— **Measurement of various parameters related to respiratory mechanics in patients assisted with mechanical ventilation is essential to provide an adequate ventilatory assistance to those patients according to their individual needs. Currently, ventilators are manufactured with the ability to acquire and visualize some basic parameters like ventilatory flow and volume and airway pressure with a tolerance error up to 20%. In this paper we present a prototype equipment, named MediVent which was developed by Universidad de los Andes and Fundación Neumológica Colombiana in Bogotá, Colombia with the ability to acquire and store simultaneously multiple parameters of ventilatory mechanics including pleural and abdominal pressures, in addition to the basic parameters measured by conventional ventilators, together with electromyography of respiratory muscles, electrocardiography, and vascular pressures. The novelty of the system resides in its ability to integrate all these parameters for real time as well as subsequent analysis by medical researchers working on ways to improve ventilatory assistance to individual patients. The measurements performed by this developed system have an error below 5% compared to a well-known certified standard, so the system itself can be used as a new standard to validate ventilators in an intensive care unit. We present the main characteristics of the equipment with emphasis on the process of validation and certification towards its use in the actual clinical setting.**

Keywords—— mechanical ventilation, volume, flow, pressure, calibration

I. INTRODUCTION

Respiratory diseases constitute today one of the highest health problems in the world exacerbated by environmental, social and demographic changes. There has been an increment of asthma, lung cancer, and chronic obstructive pulmonary disease [1-8]. Severe traumas, ischemic heart disease, cerebrovascular accidents and other neurological illnesses, generalized infections, and other diseases also lead to respiratory complications and respiratory failure. Once established, respiratory failure requires the use of assisted mechanical ventilation, and the patient must be treated in an intensive care unit or alike. As part of improvements in the treatment of critically ill patients, there is an increasing demand for more advanced forms of mechanical support of the

ventilation of those patients with state of the art respirators. In the past, it was not uncommon to set a respirator with wrong ventilatory parameters for a particular patient and condition. This situation led to inadequate ventilation of the patient, induced mechanical trauma of the lungs and airways, and the well known "fight" of the patient with the respirator. In the last 20 years, there have been significant developments in the area of assisted ventilation thanks to a better knowledge of ventilation mechanics and the technological advances in the equipment used [9-17].

Today, medical doctors and other health care professionals continue to search for more flexible ventilation systems that can adapt to the needs and conditions of every individual patient. This goal absolutely requires a deep understanding of the respiratory mechanics during ventilation, recognizing its inherent dynamic behavior [18-22]. In the last decade, "intelligent" respirators, that adapt better to the specific needs of an individual patient and reduce the risk of induced pulmonary damage, have been developed [11-14]. These respirators allowed for constant dynamic monitoring of the patient respiratory mechanics to a great extent. However, they do not provide physicians with a complete picture of the respiratory mechanics during assisted ventilation. More specifically, today no individual commercial equipment measures simultaneously in real time the various parameters that are necessary in order to have a complete understanding of that mechanics, regardless if the assistance is given in an intensive care unit or in any other hospital area dedicated to critical care like an operating or an emergency room. The current most sophisticated devices do not make measurements of some important parameters like pleural, abdominal, and transdiaphragmatic pressures. These pressures, that can be measured with balloons placed in the patient's esophagus and stomach, are important to monitor the action of the diaphragm and the patient's own respiratory activity which can conflict with the programmed assistance of the respirator. Determining the patient's own activity is critical for the physicians to be able to properly adjust the respirator settings that are most adequate to the patient's needs, particularly when the process

of removal of the mechanical ventilation is being carried out. Furthermore, for an intensive care unit, there is no individual equipment that can simultaneously measure the ventilatory parameters as flows, pressures, and volumes, together with cardiovascular parameters like arterial and central venous pressures, as well as electrocardiography (ECG) and electromyography (EMG) of respiratory muscles. The machine presented here is intended to make all these simultaneous measurements, saving them all for immediate or future analysis by the physicians who can follow the interplay of respiratory and cardiovascular parameters. We know of one machine used in Europe, the "Bicore CP-100" pulmonary monitor, that can directly measure flow in the airway (by means of a flow transducer) and esophagic pressure (by means of a catheter with an esophagic balloon) [23], but it cannot measure the other parameters mentioned above.

Our machine, named "MediVent", is a project developed between Universidad de los Andes and Fundacion Neumologica Colombiana (Bogota, Colombia) to acquire and store in one single device ventilatory parameters, cardiovascular pressures, ECG, and EMG in order to provide physicians with a more complete information of the ventilatory mechanics during assisted ventilation together with information of the cardiovascular status of the patient. The main goal is to help physicians in the process of developing more adaptable systems to assist individual patients with mechanical ventilation, reducing the risk of lung damage and other complications that result from that assistance. Additionally, the instrument must have a low cost and must be accessible to any hospital in a developing country. In this paper we describe the basic design process and the validation tests for the MediVent project. It includes the parameter acquisition selection, the main hardware and software considerations, the final implementation, the calibration process, and the validation tests, as well as the electrical safety and electromagnetic compatibility tests.

Our goal was not simply to build another equipment set that could measure parameters that are already measured separately by well-established commercial devices. Certainly, there would not be anything novel about it. Our goal was to implement an integrated system that can measure all these parameters simultaneously in a single unit and display and store them using single flexible software for real time and subsequent integral analysis by medical researchers working in a critical care unit and seeking to improve methods for ventilatory assistance. In addition, a well validated unit of this type can be used as a control standard to test and validate ventilators already in use or newly acquired in any intensive care unit.

This article is organized as follows: Section 2 describes the overall design process including the selection of the signals to be acquired as well as the selection of other calculated variables of interest to physicians working in an intensive care unit. This section describes the final design, which includes general block diagrams of the hardware and software with their main considerations as well as the industrial model design. The validation method is presented in Section 3, which

includes the calibration process for the acquisition channels, the electrical safety testing, and the electromagnetic emissions test. Section 4 corresponds to the discussion of the results and we conclude in Section 5.

II. DESIGN, IMPLEMENTATION AND FINAL PROTOTYPE

The MediVent system was developed in order to provide physicians with a more complete picture of ventilatory mechanics during assisted ventilation and help them to provide a more adequate assistance to an individual patient according to his (her) needs while reducing the risk of lung damage. The project developed between Universidad de los Andes and Fundación Neumológica Colombiana (both in Bogota, Colombia) was an interdisciplinary process that involved the participation of medical staff, a biomedical engineer, electronics and software engineers, and industrial designers.

A. High-level Definition

The process began with the medical definition of the problem briefly described in the introduction. That medical problem definition primarily determined the system high-level requirements that were essential to determine the parameters to be measured and the general system characteristics.

With the goal of acquiring as much information as possible about the patient´s respiratory mechanics and related cardiovascular parameters, we defined 10 parameters directly acquired through 10 separate channels handled by equal number of analog acquisition cards, and 6 more parameters calculated by the system's software using data from the other ten. ECG and EMG were included among those directly acquired. The parameters selected were:

Parameters to be directly acquired:

- Airway pressure.
- Esophageal pressure.
- Gastric pressure.
- Inspiratory flux.
- Expiratory flux.
- Arterial pressure.
- Central venous pressure.
- Electrocardiography.
- Diaphragm electromiography.
- Electromiography of other respiratory muscles.

Parameters calculated by the system:

- Net bi-directional air flow (Inspiratory flux – Expiratory flux).
- Volume breathed per cycle (integration in time of net flow).
- Differential or trans-diaphragmatic pressure (gastric pressure - esophageal pressure).
- Airway resistance.
- Respiratory compliance.
- Pressure-volume curve.
  The system general requirements and characteristics were:
- Development of the system as a unique structure that incorporated its own PC and monitor.

- Meeting of international standards of electrical safety and electromagnetic emissions.
- System industrial design and materials approved to be used in a medical setting.
- Easy hardware update and/or modification.
- Real-time signals visualization.
- Storage of the information in patients' files for future reproduction and analysis.
- Easy user-machine interface including operation and graphics.
- Measurement reliability and accuracy.

B. Software and Hardware Modules

The hardware module includes the acquisition cards for the ten signals directly acquired by the system. The design process for each card includes the sensor selection for the acquisition, the amplification, isolation, filtering, and a final module that controls changes in signal amplitude and offset via software (see Fig. 1.).

After the acquisition channels, the signals are passed to a digital control board to proceed with the digital treatment of the signal that implies the digitalization of the analog signals coming from the analog channels, the control of the digital potentiometers to modify signals offset and gain, and the communication with the computer (data and commands exchange). The digital architecture is shown in Fig. 2.

The microcontroller MC56F8345 receives the signals from the analog channels and digitalizes them. The signals sampling is done at 500Hz. After this process, the information is sent to the computer by means of a USB connection, for this purpose a serial-USB converter is employed. The microcontroller also sends the information to program the digital potentiometers, which change the gain and offset per channel. The microcontroller can be programmed throughout the Parallel-JTAG interface in real-time.
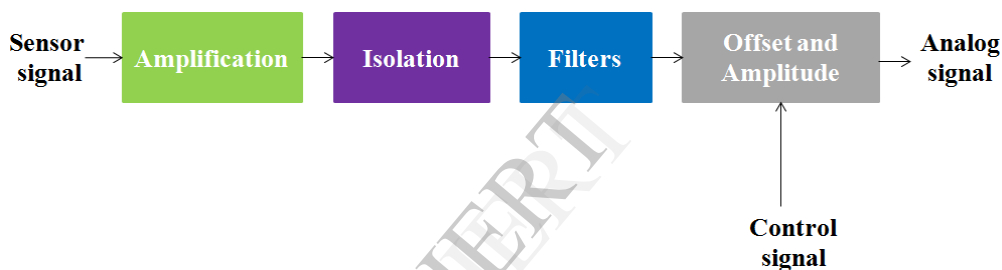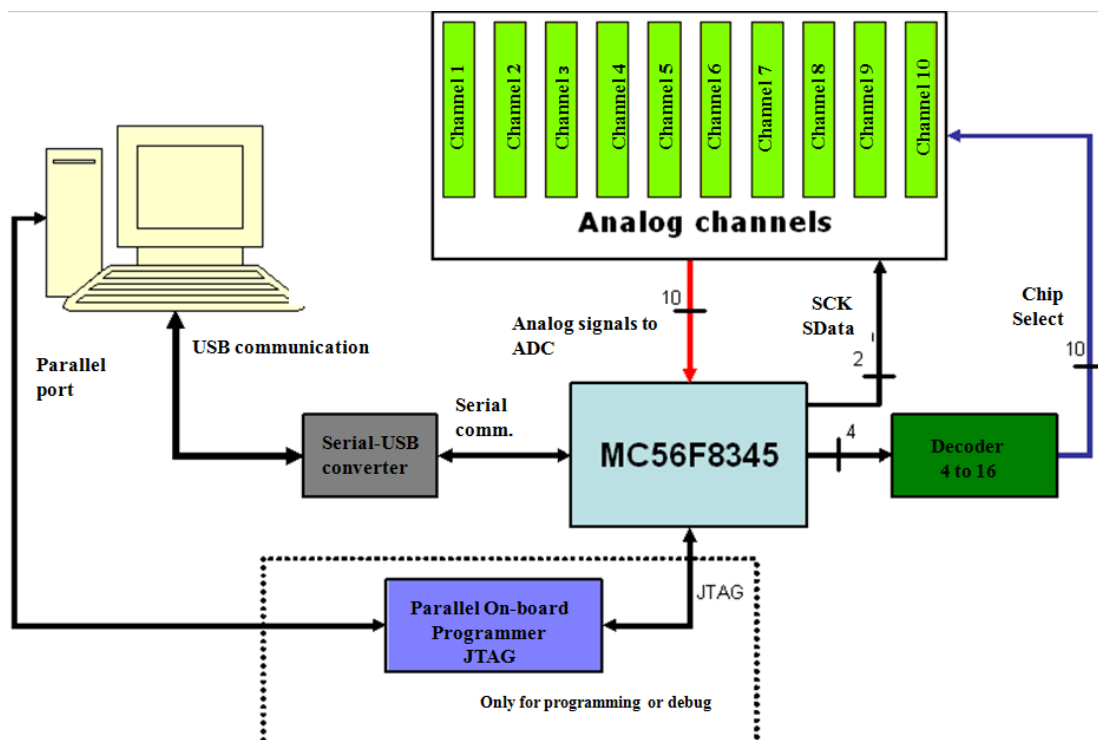

Fig. 1. Acquisition cards

Fig. 2. Digital Architecture

C. Graphic Interface and Data Management

Fig. 3 shows the block diagram developed in the Visual C++ platform to capture, process, store, and visualize the information. The software for this purpose has four principal blocks: the Monitor, MediVent DB Access, MediVent Store Handle, and MediVent Sensor Handle.

Monitor is the principal block to which other blocks are connected, its main task is the signal visualization, and the reproduction of files stored. MediVent DB Access manages the information received from the MediVent Store Handle block in the patient register as text files. The last block organize the information received from the MediVent Sensors block and relates it to the patient register. Finally, the MediVent Sensors block receives the information from the hardware acquisition cards; it also calculates the parameters not acquired directly by the system (e.g. volume).

The user-machine interface is primarily through a touch screen (see Fig. 4.). The parameters acquired and calculated are visualized in real time. The user can select the number of channels to visualize, the sweep time, the order of visualization, and also he has several options to manage the information as freeze the image, store the information, etc.
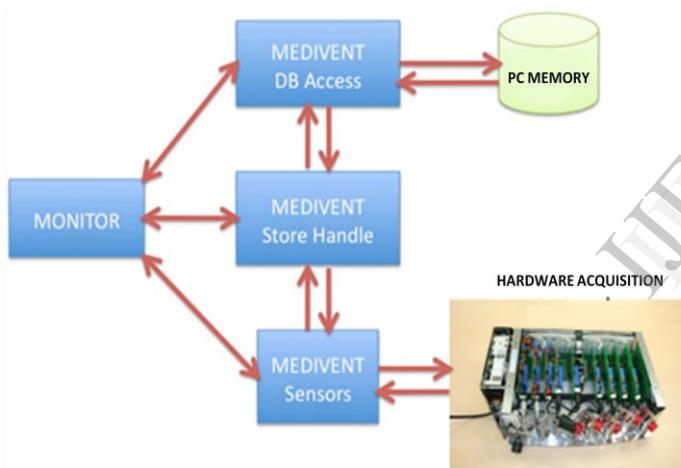
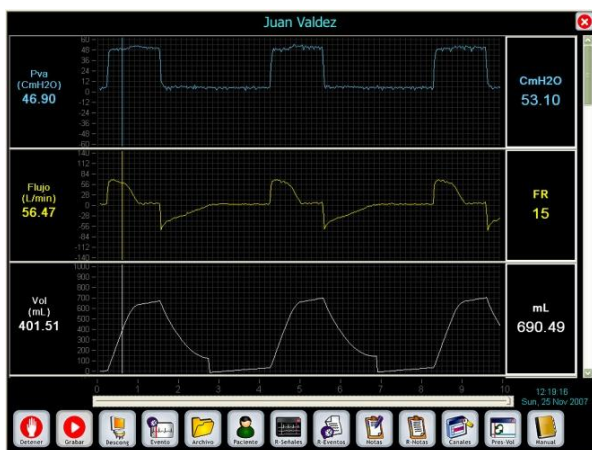

Fig. 3. Block diagram for data management

Fig. 4. Screen for the information visualization

D. Physical Prototype Structure

The physical structure was designed considering the ICU (Intensive Care Unit) facilities (e.g. cubicle distribution, patient's comfort and medical staff's comfort). Other considerations were the electronics size, the need of interconnection between ventilator, the MediVent equipment, and the patient, as well as the electrical and electromagnetic isolation. Fig. 5 shows the final presentation of the system where the sensors are divided in three groups by hoses that carry their signals: pressure sensors, ECG and EMG, and flux sensors. The touch screen is certified for use in a medical environment together with the keyboard and the hoses material. Finally, the system has wheels for easy transport.

Fig. 5. Structure

III. VALIDATION PROCESS

The validation process includes the verification of accuracy, precision, repeatability and reproducibility of the measurements made with the MediVent system. On the other hand, the verification process also includes electrical safety tests, and electromagnetic compatibility tests according to standards IEC 60601-1 and IEC 60601-1-2. In this section we present the methodology and results obtained in the validation process for each test made.

A. Inspiratory and Expiratory Flow, Tidal Volume and Peak Inspiratory Pressure Validation

To validate inspiratory and expiratory flow, tidal volume and pressure measurements, the MediVent system's measurements are compared with measurements performed in parallel with the equipment used as a certified standard under specific conditions. The ventilatory circuit used for this purpose is shown in Fig. 6, where the circuit includes a ventilator from Dragüer, the certified standard VT PLUS HF from Fluke Biomedical, the MediVent system, and an artificial lung from Siemens. The VT PLUS HF system, our standard, has known resolution and accuracy characteristics which are shown in Table 1. The artificial lung was used to simulate the air circuit connected to a patient, and had a maximum volume of 1 liter and fixed compliance.

Fig. 6. Ventilatory Circuit

TABLE I. VT PLUS Characteristics [24]

Parameter	Resolution	Range	Accuracy
Inspiratory/ Expiratory Tidal Volume	0.1 ml	As specified in high/low-flow spec	As specified in high/low-flow spec
Peak Inspiratory Pressure	0.1 cmH$_2$O	±120 cmH$_2$O	±3 % or 1 cmH$_2$O
Positive End-expiratory Pressure (PEEP)	0.1 cmH$_2$O	-5 to 40 cmH$_2$O	±3 % or 0.5 cmH$_2$O
Lung Compliance[1]	0.1 ml/ cmH$_2$O	0 – 150 ml/ cmH$_2$O	±5 or 5 ml/ cmH$_2$O
Inspiratory Time	0.01 sec	0 – 60 sec	0.5 % or 0.02 sec
Peak Expiratory Flow	0.01 lpm	0 – 300 lpm	3 % or 2 lpm
Peak Inspiratory Flow	0.01 lpm	0 – 300 lpm	3 % or 2 lpm
[1]Inspiratory pause time >0.5 sec			

The tests were performed in ascendant and descendent direction through three different magnitudes of volume (300, 500, and 700 ml) delivered by the respirator (see Table 2) according to the method utilized by the company BioSancta (Bogota, Colombia). This method uses tests and validation processes that are in compliance with the standard ISO IEC 17025:2005 [25]. Five tests were conducted with environmental conditions as temperature, barometric pressure, and relative humidity RH presented in Table 3 together with ventilator mode and ventilator model.

TABLE II. Ventilator adjustments

Size	Volume (ml)	Frequency (cl/minute)	Inspiratory time (s)
Small	300	20	0.81
Medium	500	15	0.81
Large	700	10	0.81

TABLE III. Tests' environmental

Tets	Ventilador reference	Ventilatory mode	Temperature (°C)	Relative Humidity (%)	Barometric Pressure (mmHg)
1	Evita 4 ARZK-0301	SIMV	23.55 ± 0.55	54.5 ± 2.5	562.8
2	Evita 4 ARZK-0301	SIMV	21.75 ± 0.50	55.5 ± 0.5	564.3
3	Evita 4 ARZK-0301	SIMV	24.40 ± 0.20	46.5 ± 0.5	562.1
4	Evita 4 ARZK-0301	SIMV	21.75 ± 0.15	58.0 ± 0.0	564.7
5	Evita 4 ARTA-0334	SIMV	25.15 ± 0.35	55.0 ± 1.0	563.6

A total of twenty five measurements were taken under known conditions with each of the systems: VT PLUS HF, ventilator, and MediVent. Fig. 7 shows the results found for inspiratory and expiratory flows for each volume magnitude programmed on the ventilator according to the configuration presented in Tab. 2. The graphs show the average values of all 25 samples for equipment and for each volume magnitude, together with error bars corresponding to one standard deviation. The MediVent measured flow slightly higher than the VT Plus but, in general, its measured values were closer to the standard than the ventilator.

The directly acquired channels for flow, as shown above, allow us to find the net flow from which the tidal volume is obtained. Using the same 25 measurements made for flows for each of the three volumes programmed on the ventilator, the volumes measured by the three instruments (VT Plus, MediVent, and ventilator) are shown in Fig. 8. The graph shows the averages of the 25 samples with error bars indicating one standard deviation. In the case of the ventilator, although it has been programmed for a specific volume, it also provides a curve of calculated volume from its flow measurements, and therefore, the volume measurements are not exactly the same as the volume programmed.
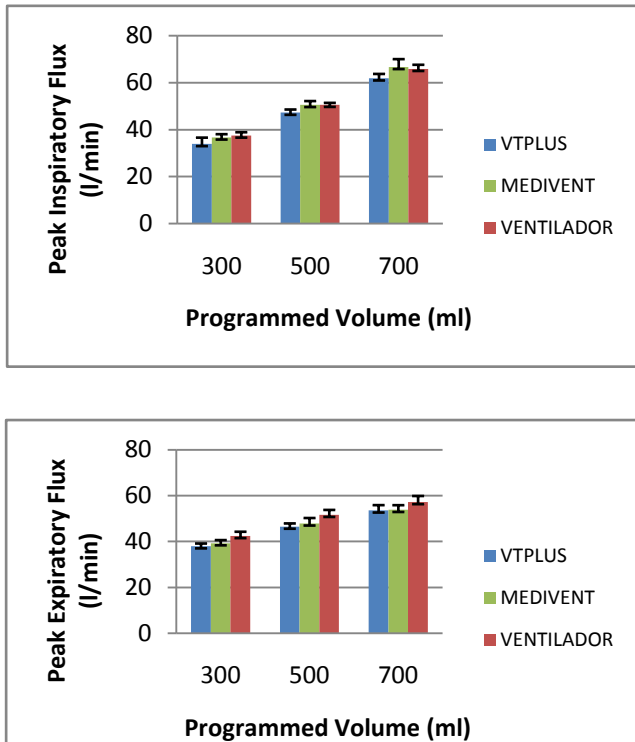
Fig. 7. Average values of inspiratory (upper) and expiratory (lower) flows measured by the three instruments for each programmed volume in the ventilator

As seen in Fig. 8, the volume measurements made by the MediVent were closer to the certified standard we used, the VT Plus, than the measurements made by the ventilator itself. Specifically, comparing averages, the maximum error of the MediVent equipment was 2.45% with respect to the VT Plus, while the maximum error for the ventilator was as high as 12.45% (at 700 ml).
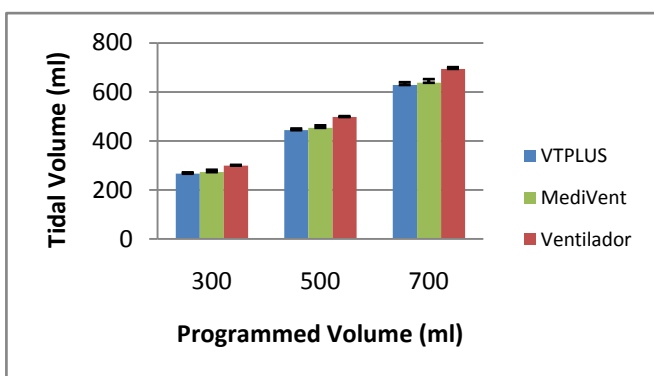

Fig. 8. Average values of inspiratory and expiratory flows measured by the three instruments for each programmed volume in the ventilator.

Fig. 9 shows the results for the peak inspiratory pressure taken at the connection of the artificial lung, simulating a patient's airway pressure. The graph shows the average values for each of the three instruments used and for each of the three programmed volumes. The error bars correspond to one standard deviation.

In the case of the pressure measurements, and again comparing the averages, the maximum error of the MediVent equipment was 5.2% with respect to the VT Plus, while the maximum error for the ventilator was 1.73%. The error for the MediVent was due to a constant offset in the sensors that was not taken into account when the validation tests were performed. That offset at normal ambient pressure is being corrected, and that correction will bring down the maximum error below 2% when comparing to the standard.
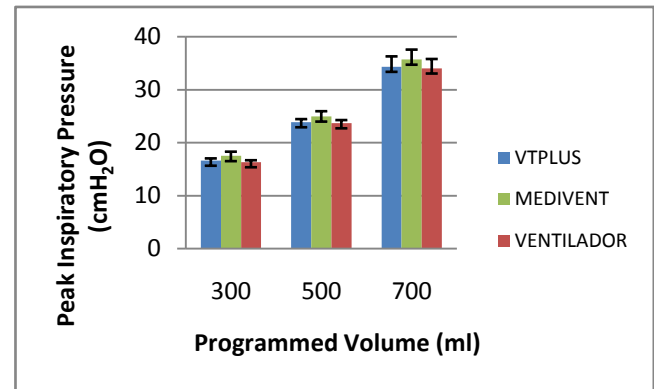

Fig. 9. Average values of peak inspiratory pressures measured by the three instruments for each programmed volume in the ventilator

In addition to comparing averages between MediVent and Ventilator with respect to the certified standard, we examined the repeatability or reproducibility of the measurements for the MediVent. For this purpose we performed a statistical analysis utilizing the software SAS (Statistical Analysis System). Splitting randomly the 25 samples in two groups (A and B) for the volumes and peak inspiratory pressures measured by the MediVent for each programmed volume, we performed a T-Student test with the null hypothesis that there is no difference between the two groups of samples with a 95% confidence interval. Tables 4, 5, and 6 show the results for the three programmed volumes. The high p values from 0.8 up to 0.98 allow us to confirm the null hypothesis that there is no difference between the two groups of samples taken at different times and that the measurements are repeatable and the measurement method is reproducible over time.

TABLE IV. STATISTICAL ANALYSIS FOR 300ML

	Sample Statistic				
Volume 300ml	**Group**	**N**	**Mean**	**Std. Dev.**	**Std. Error**
	A	13	268.0	6.56	1.69
	B	12	268.6	5.76	1.49
	Hypothesis Test				
	If variances are	**t-statistics**		**Df**	**Pr>t**
	Equal	-0.26		28	0.80
	Not Equal	-0.26		27.539	0.80

	Sample Statistics				
Peak Inspiratory Pressure 300ml	**Group**	**N**	**Mean**	**Std. Dev.**	**Std. Error**
	A	13	17.48	0.74	0.20
	B	12	17.50	0.88	0.27
	Hypothesis Test				
	If variances are	**t-statistics**		**Df**	**Pr>t**
	Equal	-0.06		23	0.95
	Not Equal	-0.06		19.44	0.95

TABLE VI. STATISTICAL ANALYSIS FOR 700ML

	Sample Statistics				
Volume 700ml	**Group**	**N**	**Mean**	**Std. Dev.**	**Std. Error**
	A	13	637.8	14.59	4.05
	B	12	637.5	13.66	3.94
	Hypothesis Test				
	If variances are	**t-statistics**		**Df**	**Pr>t**
	Equal	0.06		23	0.95
	Not Equal	0.06		22.99	0.95

	Sample Statistics				
Peak Inspiratory Pressure 700ml	**Group**	**N**	**Mean**	**Std. Dev.**	**Std. Error**
	A	13	35.68	1.99	0.55
	B	12	35.71	1.77	0.51
	Hypothesis Test				
	If variances are	**t-statistics**		**Df**	**Pr>t**
	Equal	-0.03		23	0.98
	Not Equal	-0.03		22.97	0.98

TABLE V. STATISTICAL ANALYSIS FOR 500ML

	Sample Statistics				
Volume 500ml	**Group**	**N**	**Mean**	**Std. Dev.**	**Std. Error**
	A	13	453.8	9.26	2.57
	B	12	453.6	9.64	2.78
	Hypothesis Test				
	If variances are	**t-statistics**		**Df**	**Pr>t**
	Equal	0.04		23	0.97
	Not Equal	0.04		22.65	0.97

	Sample Statistics				
Peak Inspiratory Pressure 500ml	**Group**	**N**	**Mean**	**Std. Dev.**	**Std. Error**
	A	13	24.98	0.88	0.24
	B	12	24.93	1.07	0.31
	Hypothesis Test				
	If variances are	**t-statistics**		**Df**	**Pr>t**
	Equal	0.12		23	0.91
	Not Equal	0.12		21.33	0.91

B. ECG and EMG Validation

The validation of the ECG channel (see Fig. 10) was performed by taking an ECG signal from a Patient Simulator (Fluke Biomedical model MPS 450, calibrated and certified) and verifying the wave shapes and the measured cardiac frequency. The Patient Simulator characteristics are shown in Table 7.

TABLE VII. PATIENT SIMULATOR'S CALIBRATION CERTIFICATE

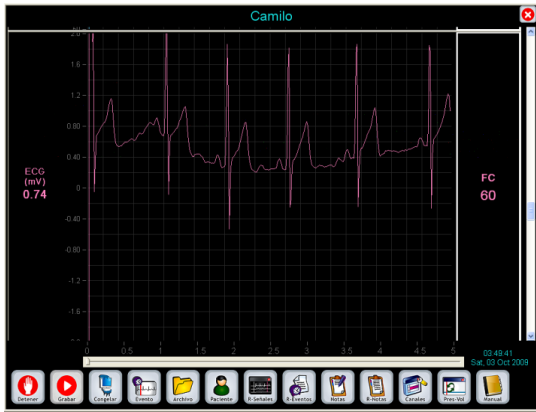| Specifications Frequency BPM	Frequency measured	Frequency tolerance	Frequency Uncertainty
60	60.000	0.6	±0.02310123
120	120.000	1.2	±0.02310123
180	180.6000	1.8	±0.02310123
240	238.200	2.4	±0.02310123
300	300.000	3	±0.02310123

Fig. 10. Acquisition and visualization of an ECG signal with the MediVent equipment.

Five cardiac frequencies were tested both in ascendant and descendant orders according to the method utilized by the company BioSancta in compliance with the standard ISO IEC 17025:2005 [25]. Table 8 shows the cardiac frequencies measured by the MediVent compared to the simulator with the corresponding errors which were not greater than 1.2. The values showed are the average of 10 samples.

TABLE VIII. ECG FREQUENCIES MEASURED BY THE MEDIVENT EQUIPMENT COMPARED TO THOSE GENERATED BY THE SIMULATOR

ECG simulation	Frequency measured	Frequency error	Frequency Uncertainty
60 BPM or 1Hz	60.0	0	±0.57781225
120 BPM or 2Hz	118.8	-1.2	±3.92805969
180 BPM or 3Hz	178.8	-1.2	±3.92805969
240 BPM or 4Hz	239.4	-0.6	±1.84892966

To validate the EMG channels and their application, two tests were performed. For the first one, selected signals were generated by the patient simulator; and for the second one, surface electrodes were placed on the thorax of a human volunteer in order to measure electrical activity of the diaphragm during inspiration. For the latter test, in order to minimize any ECG signal interference with the EMG of the diaphragm and also to minimize any 60 Hz noise, a high pass filter above 40 Hz and a notch filter at 60 Hz had been implemented in the hardware. The electrodes on the human volunteer were placed as described in the literature [26] as follows: one electrode was placed 5 cm above the Xiphoid appendix, other two electrodes were placed along the costal margin at 16 cm from the one previously described (one on the left side and one on the right side of the patient), and finally one ground or reference electrode was placed midway between the xiphoid appendix and the sternum handle. The placement of the electrodes for this test is shown in Fig. 13.

To test the filters used for the EMG channel, the patient simulator was used to generate different signals that were displayed by the MediVent as shown in Fig. 11. The figure shows the same EMG channel with various signals in the following sequence from top to bottom: 1) no signal, 2) a random signal with frequencies above 40 Hz, 3) a 60 Hz signal (minimized by the notch filter), and 4) a modulated broad band random signal.
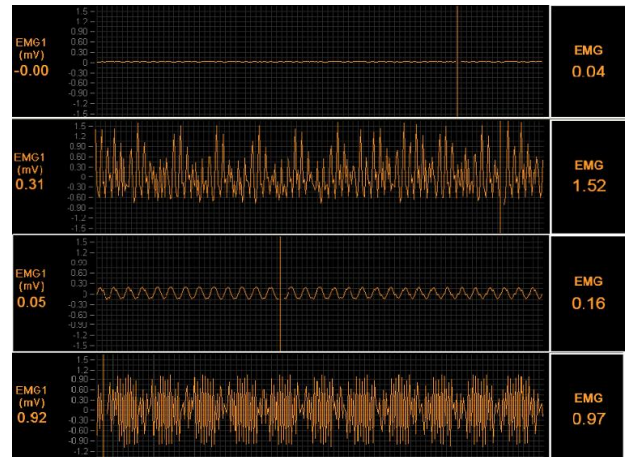

Fig 11. Signals generated by a patient simulator to test the filters for the EMG channel.

The actual test for electromyography of the diaphragm on a human volunteer is shown in Fig. 12. The activity of the diaphragm is visualized as an increase in the amplitude of the signal above noise level during a normal (not forced) inspiration of the person.
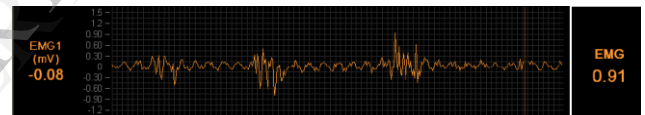

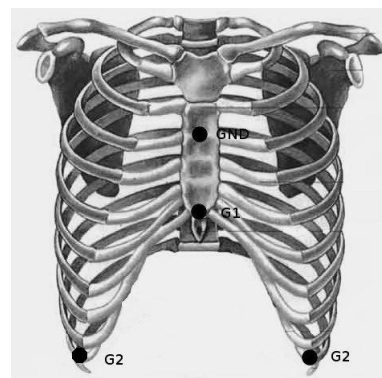Fig 12. Detection of the diaphragm activity in a human subject during inspiration

Fig 13. Diap   EMG Electrodes.

C. Tests for Electrical Safety and Electromagnetic Compatibility

The test of electrical safety for any electromedical equipment is required in order to confirm that the equipment follows the standards for protection of the patient, the operator, and any other personnel in the surroundings. The risk of electrical discharge is evaluated for conditions of first

defect (neutral line open), second defect (ground line open), and third defect (inverted phase and neutral) according to the Norm IEC 60601-1 [27]. For these tests we used the electrical safety analyzer from Fluke Biomedical model ESA601 making the connections shown in Fig. 14. Five measurements were made for each safety parameter tested. The results of the tests are shown in Tab. 9. comparing them with the values specified by the norm. The table has three columns: the first one for the norm, the second for the average of 5 measurements, and the third for the maximum deviation of any measurement from the average.

Fig 14. Electrical safety test (circuit implementation).

TABLE IX. RESULTS OF THE ELECTRICAL SAFETY TESTS

Parameter	Specifications	Measured Value	Variation Range
AC supplied voltage (VAC)	117	121.12	± 3.032
Leakage current to ground (µA)	≤ 500	394.2	± 10.32
Leakage current to ground with condition of first failure (µA)	≤ 1000	675.6	± 16.77
Leakage current to chassis (µA)	≤ 100	0.4	± 1.17
Leakage current to chassis with condition of first failure (µA)	≤ 500	0.5	± 1.172
Leakage current to chassis with condition of second failure (µA)	≤ 500	0.5	± 1.172
Leakage current patient ECG to ground (µA)	≤ 10	0.3	± 1.167
Leakage current patient electrode ECG to ground with condition of first failure (µA)	≤ 50	0.3	± 1.167
Leakage current patient electrode ECG to ground with condition of second failure (µA)	≤ 50	1.8	± 1.202
Leakage current patient electrode ECG to ground with condition of third failure (µA)	≤ 50	0.3	± 1.167

Auxiliary current electrode ECG (µA)	≤ 10	0.7	± 1.177
Auxiliary current electrode ECG with condition of first failure (µA)	≤ 50	0.8	± 1.179
Auxiliary current electrode ECG with condition of second failure (µA)	≤ 50	0.8	± 1.179
Auxiliary current electrode ECG with condition of third failure (µA)	≤50	2.6	± 1.22
Resistance to ground (Ω)	≤0.2	0.2556	± 0.023

The only parameter that was slightly above the norm (resistance to ground) was corrected by changing the line connection to the main power supply.

The tests for electromagnetic compatibility characterize the radiated emissions from the MediVent equipment according to the guide for the norm CISPR 11 [28] in the frequency range from 20 to 200 MHz and 200 to 1000 MHz. Electromagnetic compatibility tests are essential for any biomedical equipment, and particularly for an equipment that will operate in an intensive care unit or any other area for patient critical care. The MediVent equipment is classified in Group 1, Class A whose limits for electromagnetic emission, measured in a standard test site, are shown in Tab. 10.

TABLE X. LIMITS OF ELECTROMAGNETIC EMISSION ACCORDING TO THE NORM CISPR [28]

Frequency range (MHz)	10 m measuring distance rated input power of	
	≤20kVA	>20 kVA
	Quasi-peak dB(µV/m)	Quasi-peak dB(µV/m)
30 – 230	40	50
230 - 1000	47	50

The tests for this type of emissions were performed in the controlled environment of an anechoic chamber (at the University of los Andes in Bogota) in the semi-anechoic configuration (on ground plane). The MediVent equipment was placed on the ground plane in the anechoic chamber as shown in Fig. 15, with the typical electrode and sensor connections in the usual configuration of operation. These electrodes and sensors were placed on a box at a height of 1.2 m, simulating the location of normal operation. During the tests, the equipment was kept on and acquiring data. The measurements were performed using the Log-periodic antenna ETS-L indgren 3104C (see Fig. 16) for a frequency range of 200 to 1000 MHz and a Biconic antenna ETS-L indgren 3104C for a frequency range of 20 to 200 MHz. The MediVent equipment was located 3 m from the antenna in use which was placed at three different heights: 1.2, 2, and 3 m. The measurements are made for the four sides of the

MediVent equipment (azimuth angles: front, back, left side, and right side) facing the antenna.

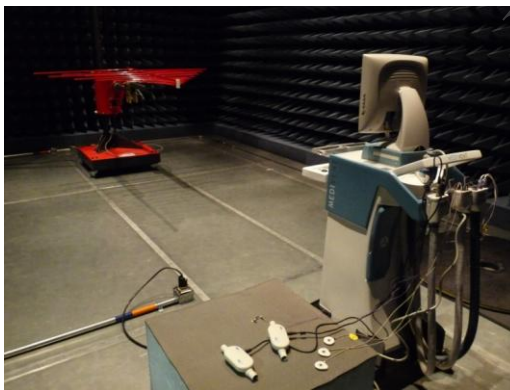Fig. 15. Placement of the MediVent equipment and its sensors on the ground plane of the anechoic chamber

Fig 16. Placement of the Log-periodic antenna ETS-L indgren 3104C .

The data were registered by means of a spectral analyzer connected to the respective antenna and located outside the anechoic chamber. Horizontal and vertical polarizations were registered and then fulfillment of the norm was verified taking into account the 3 m distance of the real measurements versus the 10 m distance used for the limits given by the norm and presented in Table 10. In order to determine the limits of the norm for 3 m, Eqn. (1, 2) were used [29-30]:

$$Rc = Rr + Fd \qquad (1)$$

where Rr corresponds to the limits of the norm in dB(μB/m), Fd is the distance factor in dB, and Rc corrected limit in dB(μB/m). The distance factor is obtained from:

$$Fd=20\log(Ds/Dm) \qquad (2)$$

where Dm is the measurement distance in meters and Ds is the distance specified by the norm also in meters.

According to the equations above, and considering that the power of the MediVent equipment is ≤20 kVA, the new emission limits adjusted for a distance of 3 m, compare to those at 10 m, are exposed in Tab. 11.

TABLE XI. MODIFICATION OF THE LIMITS OF THE NORM CISPR 11 FOR A MEASUREMENT DISTANCE OF 3M

Frequency range (MHz)	10m Quasi-peak dB(μV/m)	3m Quasi-peak dB(μV/m)
30 – 230	40	50.46
230 - 1000	47	57.46

Fig. 17 shows the worst case for electromagnetic emission from the MediVent as detected by the biconic antenna for frequencies from 20 to 200 MHz. According to the limits of the norm shown in Table 11 at 3 m, emissions are below the limits for most of these frequencies except between 47 and 50 MHz and above 172 MHz where emissions reached 53 dB(μV/m), above the 50.46 dB(μV/m) limit of the norm.
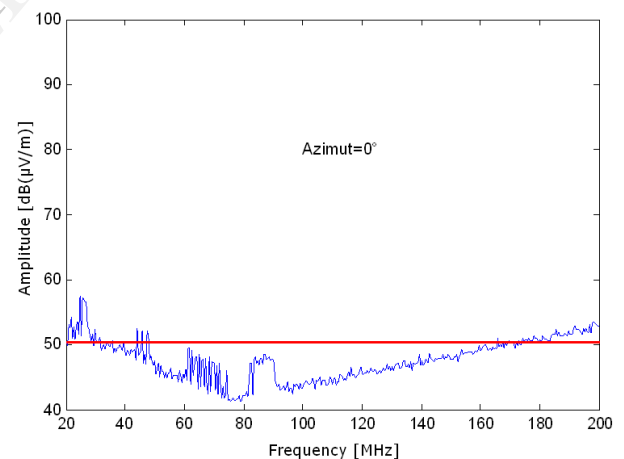

Fig. 17. Emissions detected by the biconic antenna for frequencies from 30 to 200MHz. The red line corresponds to the limit given by the norm.

Fig. 18 shows the worse case for electromagnetic emission from the MediVent as detected by the log-periodic antenna for frequencies from 0 to 1000 MHz. According to the limits of the norm shown in Table 11 at 3 m, emissions are below the limits for most of these frequencies except above 730 MHz where emissions reached 61 dB(μV/m), above the 57.46 dB(μV/m) limit of the norm.
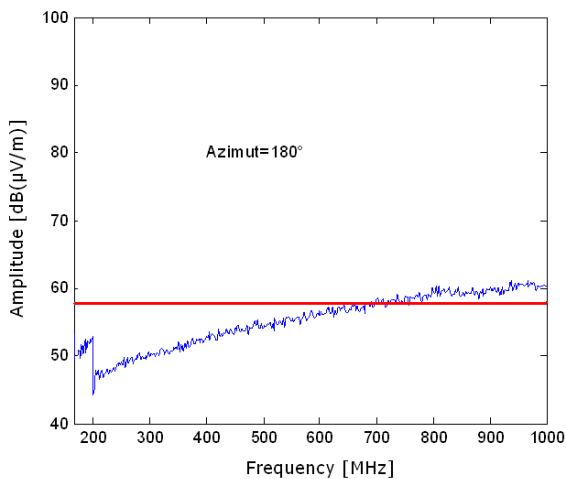
Fig. 18. Emissions detected by the log-periodic antenna for frequencies from 200 to 1000MHz. The red line corresponds to the limit given by the norm

IV.   DISCUSSION

The MediVent equipment has been validated against a certified standard with maximum error not higher than 2.5% for volume measurements and not higher than 5.2% for pressure measurements with respect to that standard which itself has a specified uncertainty of 3%. The maximum error mentioned above for pressure measurements is due to an uncorrected offset of the pressure sensors at the ambient conditions of the city of Bogota. That offset is now being taken into account and the error is expected to fall below 2%, as proven through other tests performed with a water column in a tube.

The reproducibility of the MediVent has also been demonstrated with measurements taken in different days by different operators, locations, and ventilators delivering the air volumes. With corrected baseline offsets and an additional electromagnetic isolation of the electronics enclosure, the MediVent equipment can be certified to become our standard to test different types of ventilators used to assist patients in critical care areas.

In general, this equipment, that combines measurements of ventilatory and cardiovascular parameters will be extremely useful in intensive care units and other units of critical care as well as in units dedicated to the study and analysis of ventilatory mechanics. In the Intensive Care Unit, visualization in real time of all the parameters measured and calculated by the MediVent, with the option of recording them or not, will allow physicians to determine if the ventilatory assistance to the patient is adequate and perform adjustments to the ventilator as he (she) finds necessary. No commercial ventilator or other single equipment can measure, visualize, and record all these parameters simultaneously.   A second phase of this project will include the addition of pulse oximetry for monitoring of oxygen saturation. The current capability to detect activity of the diaphragm is essential to monitor individual patient active response and to adjust the mechanical assistance of the ventilator according to patient needs. We plan to optimize and expand this capability which could also be used to monitor other respiratory muscles and even other skeletal muscles for physiological tests. Pulmonologists and critical care physicians can use this equipment for institutionally approved studies and research, which is perhaps the main strength of the MediVent. The equipment is extremely user friendly, the design of the graphics interface has been praised by the physicians, respiratory therapists, and other health care professionals that have had a chance to use it. The operator decides the order of the channels to be visualized and how many channels to visualize simultaneously on a single screen, being able to scroll to see the other channels at will. Data are recorded in a text format so it can be exported and opened in other common applications for graphics like Excel. The software flexibility allows us to easily implement additional changes suggested by physicians. In addition, the implementation of this equipment has been done at very low cost when compared to other commercially available medical equipment, making it quite affordable for hospitals in developing countries.

V.   CONCLUSION

A system, which we named MediVent, that makes measurements of various parameters of ventilatory mechanics together with EMG of the diaphragm and vascular parameters has been implemented and validated against a certified standard. The system is novel in its ability to acquire and store simultaneously all these parameters in a single file that medical researchers can easily access and analyze. Parameters like pleural and abdominal pressures, together with electromyography of respiratory muscles are not measured by conventional equipment available in intensive care units. Having this capability, our system can provide physicians with additional vital information that will help them improve assistance to individual patients treated in any unit dedicated to critical care. Also, this MediVent system can now be used as a new standard to test and validate ventilators already in use or newly acquired in any intensive care unit.

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