A NEW PRACTICAL SCHEME FOR VERIFICATION OF PULMONARY VENTILATORS USED IN HUMAN MEDICINE

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Abstract – The ventilation equipment's proper operation is mandatory to ensure the medical act's success. The pneumatics lung ventilator testing is not standardized, and it is established by the manufacturers. The usual ventilators test systems can't measure accurately all the ventilators parameters. This paper proposes a test unit that can be used for a big ventilation equipment majority. This system follows to measure the ventilator's parameters that can't be accurately measured by conventional systems.

***Keywords*:** test equipment, lung ventilator

1. Introduction

The ventilator is the equipment that sustains the patient breathing when he totally or partly loses the respiratory function. Whereas it is vital to maintain the patient in life, it has to be known whether the ventilator works or not in the designed parameter ranges stipulated in the technical documentation.
The ventilation systems producers have developed their own test systems. There are international standards that provide the tests that should be performed for the equipment's electrical safety. Typical electrical measurements are performed according to standards IEC 60601, IEC 62353.
In the human ventilator's pneumatics area there are no specific standards, for the moment.
The ventilators usually have incorporated various types of sensors (e.g. pressure, flow, temperature, CO2 concentration, O2 concentration) that monitor various parameters. The producer's tests refer to verifying sensor calibration voltage and check the sensor's response for different values, standardized by each producer, with calibrated and verified metrology equipment. For a better evaluation of the ventilator the system should be tested by introducing values that should simulate critical situations to verify the occurrence of certain alarm states.
The main measuring and testing parameters are [1]:

• **The pressure:**
o p_{max} (the maximum pressure) - a high pressure fluid can damage the lungs, especially for the newborns,
o PEEP (the Positive End-Expiratory Pressure) - can lead to alveoli collapse, when it is too small, or at an insufficient exhale level, for high PEEP levels,
o $p_{plateau}$ (the plateau pressure) – plateau pressure witch shows the pressure level for a given tidal volume,
o $p_{trigger}$ (the trigger pressure in the patient's circuit) – shows the "loading" probability and provides information about the need to change the ventilation mode,
o p_{mean} (the mean pressures during the ventilator cycle) - shows the fluid pressure introduced into the lungs and provides information about the maximum pressure level that can decrease or not.
• **The volumes:**
o VT_i (Inhale Tidal Volume) – the gas volume delivered by the ventilator into the patient's lungs and shows, comparing it with the VT_e (exhale tidal volume) the leakage level and the intubation's quality,
o VT_e (Exhale Tidal Volume) - shows how efficiently the patient is ventilated,
o MV (Minute Volume) - shows how well the patient is ventilated over time, unlike the quality of the VT_e that ilustrates the ventilaion quality for a single breath.
• **The frequency**:
o t_{inhale} (inhale time) – together with the t_{exhale} (exhale time) influences the I:E ratio level (the inhale - exhale ratio),
o t_1 – the inhale time period in whitch the gas is introduced into the lung,

o t_2 – the inhale time period in whitch while the VT (tidal volume) is kept constant (the gas does not enter),
o t_{exale} – exhale time,
o f – frequency (respiratory rate),
o f_{spont} (spontaneous frequency) – is the spontaneous breathing level and describe if the chosen ventilation mode is adequate.
- The gases concentration:

o inhaled gas O_2 concentration – is the ventilator's "loading" level that needs to relate to the body's oxygen demand,
o exhaled gas CO_2 concentration – the ventilation level related to the hyper or the hypo-ventilation**,**
o anesthetic gas concentration – represents the patient's sedation level.
• The inhaled gas temperature - the inhaled gases temperature level for a successful thermoregulation.

2. Classical Testing. General Information

Testing the pulmonary ventilators is done using lung simulators. Pressure values are achieved connecting a manometer in parallel with the lung simulator [2] - [4]. The technician monitors the maximum and minimum pressures. The plateau pressure determination requires an experienced technician. He must oversee the lungs's filling state and consider the plateau pressure the value for which the lung is maintained inflated.
The volumes check is done by reading the VT (Tidal Volume) value on the ventilator's display and compare it with the seted one.
The techician establishes the inhale and the exhale time with a stopwatch by pressing start and stop at the inhale and exhale beginning and end. The measurement is not accurate because it depends very much on the human factor. The smaller respiratory times determination can not be achieved because of the technician increased time reaction (as in neonates).
The frequency is determined by starting a timer at the begining of an inhale phase and counting the inhale number for one minute. The t_1 and t_2 times can hardly be determined. They are determined only by viewing the guide filling and maintaining the inflated lung simulator.
The oxygen concentration is determined by connecting the oxygen concentration sensor to the inhale deviation.
The temperature is determined by mounting a thermometer on the inhale deviation.

3. Testing a Ventilator Type

To demonstrate it is shown a Savina equipment test system [2].
The check consists of:

- checking various subset unit series numbers,
- checking data equipment,
- checking user settings,
- checking the general state of the ventilator,
- testing electrical safety and power supply,
- testing keyboard and display,
- testing inhale and exhale blocks.

To test the ventilation equipment the following measure schemes are used.
Using the syringe 1, slowly (permissible pressure change less than 1 mbar/s) build up a pressure of 2.5 mbar ±0.5 mbar at the outlet of the exhale valve. The volume injected through the syringe in one minute must not exceed 35 ml. Pressure is monitored by pressure gauge 2, connected in parallel with expiratory valve 4 by connector 3 and "T" shape piece 5.

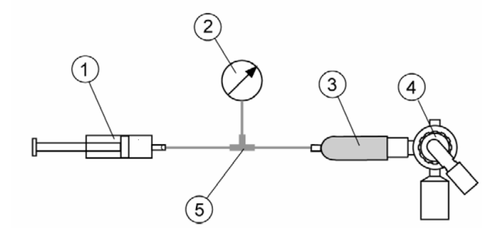

Fig. 1 Diagram for testing the non-return valve in the exhale block

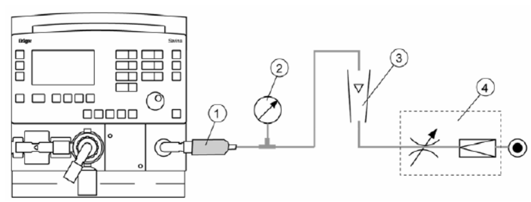

Fig. 2 Inhale block safety valve check diagram

A flow regulator 4 is generating gas at a flow rate of 2-3 l/min. It is determined by the flow meter 3. The pressure reading from the pressure gauge 2, which is connected through the connecting sleeve 1 to the inhale valve, must be in the 80 -120 mbar range.

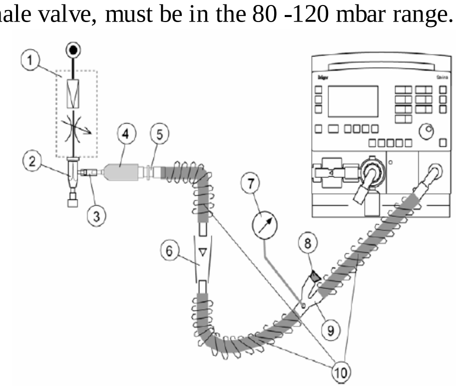

Fig. 3 Inhale block emergency valve check diagram

A fluid flow of 59 to 61 l/min is generated through the flow meter 6 using a test pressure regulator 1 and injector 2. The pressure monitored by the pressure gauge 7 should be in the [-6, -3] bar interval. The hoses 10, the "Y" - piece 9, the sealing plug 8, the silicone tube 3, connecting sleeve 4 and ISO socket 5 are used to enable the assembly.

- ventilation testing:

The IPPV mode is set, VT=500ml, t_i=2s, f=12breath/min, PEEP = 5mbar, FiO_2=21%, and the values provided by ventilation equipment are read on the display. The values are checked to be in tolerance ranges provided by the producer. A different value for the oxygen concentration FiO_2=60% is chosen and the measured value is read and shown on the display. This value is compared with the determined value from the oxygen analyzer 2 that is mounted in parallel with the patient 5 through the "T" shape piece 1. The PEEP pressure is check with the pressure gauge 6 connected to the patient 5 through the "Y" piece 4 and the hoses 3.

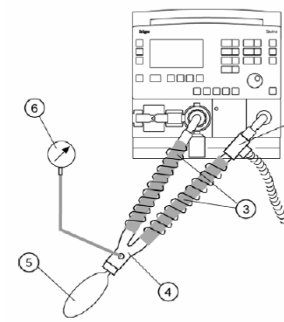

Fig. 4 Ventilation testing diagram

The BIPAP mode is chosen, and the following values PEEP=5mbar, t_i=5s, f=6breth/min, p_{inhale}=5mbar, and the values provided by the ventilation equipment are read on the display. These values are compared with the p_{inhale} and PEEP read on the pressure gauge 6, and checked if they are in the tolerance range from the producer's service manual.

The volumes are verified by comparing the VT_i to the VT_e and the volumes should not differ by more than 15%.

4. Conclusions on the Classical Testing

In classical ventilator testing it can be seen that the VT_i, VT_e and MV values are verified only with the ventilator's sensors, by comparison, but there is no certainty that the ventilator's flow sensors are in normal ranges or not.

Classical testing can not determine the frequency and inhale and exhale times. All data about those times are available only on the ventilator's display. In some cases these times are determined by the technician. In such cases only the inhale and exhale times and frequencies are determined, but with the technician's response time errors. The plateau time can not be determined.

The pressures are determined by reading the maximum and the minimum value on a manometer connected in parallel with the patient and compared with those displayed by the ventilator. The maximum and the PEEP pressure can not be exactly determined. The plateau and the mean pressure can not be monitored externally.

For oxygen concentrations, temperatures and anesthetic concentrations testing are required other equipment.

The human factor, the one that generates a lot of errors is quite present in the various parameters determination.

As a results of the previous observations its obvious the need for a new and complex system that would be able to determinate the pressures (PEEP, p_{inhale}, p_{exhale}, $p_{plateau}$, Δp_{ASB}), the inhale and exhale volumes (VT_I, VT_e), Minute Volume (MV), the inhale and exhale times (t_I, t_e), the frequency (f) and the inhale: exhale ratio (I:E), the oxygen concentration (FiO_2), the anesthetic and CO_2 concentrations, and the gas temperature.

5. Proposal for a Lung Ventilator Verification System

This paper presents a lung ventilator verification system designed for fast and accurate breathing equipment checking.

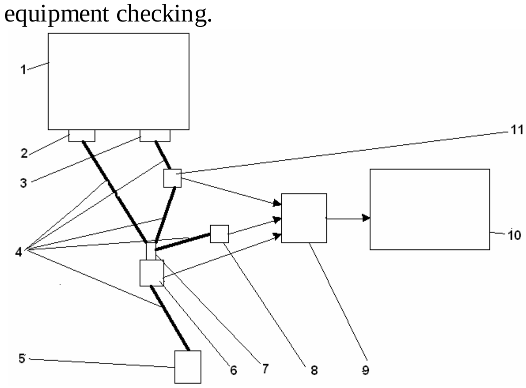

Fig. 5 The test system diagram

The ventilator's test system shown in Fig. 5 consists, mainly, of the pressure sensor 8, the flow sensor 6 and the oxygen concentration sensor 11 connected through the data acquisition card 9 to the computer 10, on which is installed the LabView software. The oxygen concentration sensor 11 is connected to the ventilator circuit, consisting of hoses 4, between the inhale block 3 and the "Y" piece 7. The pressure sensor 8 is connected via a hose directly to the "Y" piece 7 and the flow sensor 6 is connected between the lung simulator 5 and the "Y" piece 7.

The ventilator 1 introduces the inhaled gas at a preset flow and pressure values by the inhale block 3. The gas is analyzed in terms of oxygen concentration by the oxygen concentration sensor 11. Depending on the oxygen concentration in the inhaled gas it provides a certain electric voltage to the data acquisition card 9. Its value is read using the LabView software and displayed on the computer's display 10. The pressure in the patient system 4, is determined almost constant by the pressure sensor 8. Sensor 8 provides various electrical signals, for various pressures, which are viewed through the data acquisition card 9 and the LabView software on the computer's display 10. The gas flow rate is determined by the sensor 6 and viewed on the computer's display 10 similarly to the pressure rate. All data are retrieved and displayed in real time.

The exhale is made by the ventilator through the exhale valve 2. The gas pressure and flow are monitored by the exhale pressure sensor 8 and by the flow sensor 6 and their values are viewed on the computer's display 10.

For the proper functioning of the system a computer program is developed in the LabView software [5] - [7]. This program is converting electrical voltages from the oxygen concentration, pressure and flow sensors into oxygen concentration, pressure and flow values. The computer also processes the data received from the sensors and provides the values of the main respiratory parameters (the maximum pressure, the PEEP, the plateau pressure, the VT, the inhale and exhale times, the respiratory rate, the inhaled gas oxygen concentration).

The ventilator on which determinations were made with this scheme is a Dräger Savina. The Savina equipment has been previously tested according to the manufacturer's documentation and has passed all tests.

The main features of this ventilator are presented in Table 1.

Table 1. Features of the Dräger Savina ventilator

feature	the feature's value
Respiratory rate [/min]	2-80
t_{inhale} [s]	0,2- 10
gas flow [l/min]	0-180
VT [ml]	50-2000
accuracy flow	±10%
p_{inhale} [hPa]	0-99
PEEP [hPa]	0-35
O_2 [%]	21-100

6. This Paper's Developed System Constituent Parts

To create the testing system the following parts were used:

Pressure sensor: SQ 99835 Honeywell type [8]

Fig. 6 Pressure sensor SQ 99835 (Honeywell)

Flow Sensor: Honeywell AWM5000 [9]

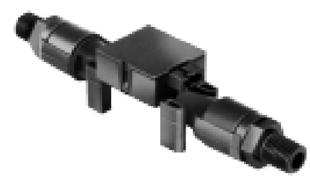

Fig. 7 Flow sensorAWM5000 (Honeywell)

Oxygen sensor: Dräger Mainstream

Fig. 8 Oxygen sensor Dräger Mainstream

The data Acquisition Card is an USB 6009 type - produced by the National Instruments.

Fig. 9 Data Acquisition Card USB 6009

7. Conclusion

This testing system can be used for most of the ventilation equipment.

There is only one test equipment.

The system's flow and pressure sensors are different from those of the ventilation equipment and such they can check the ventilator's sensors (by comparison).

This system automatically determine all the parameters (p_{max}, PEEP, $p_{plateau}$, $p_{trigger}$, VT_i, VT_e, MV, t_{inhale}, t_1, t_2, t_{exhale}, inhaled gas O_2 concentration) without human error. The parameters are determined automatically by the system, the only error being given by the sensor's precision and calibration and by the sampling rate.

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