AN INNOVATIVE EXPERIMENTAL SYSTEM TO TEST RESPONSE TIME AND RELIABILITY OF NEONATAL FLOW-TRIGGERED VENTILATORS

by F.P. Branca, P. Cappa, and S.A. Sciuto

Response time and trigger sensitivity of flow-triggered ventilators are fundamental parameters to objectively evaluate these risk electromedical devices or to test their working efficiency. In order to measure the previously indicated fundamental parameters, an innovative experimental setup is proposed. To trigger the tested machine, a specific neonatal patient simulator system capable of moving known air volumes in the field from −1 to 1 ml, according to a chosen temporal function, has been realized and calibrated. An automatic measuring system controlled by an AT PC via IEEE-488 and allowing 10 kHz sampling frequency has been adopted to measure flow and trigger signals directly picked up from the examined ventilator. Two different flow triggered neonatal ventilators are tested in order to prove the effectiveness of the proposed method and results are reported.

INTRODUCTION

Ventilators are extensively utilized in intensive care and anaesthesia to compensate for deficiencies in normal breathing. A ventilator may aid or augment spontaneous breathing or may regulate completely a prescribed breathing pattern for patients who can not breathe for themselves. There are five main respiratory patterns[1] for premature infants: (1) apnea; (2) augmented inspiratory reflex; (3) active expiratory reflex; (4) spontaneous asynchronous breathing; (5) synchronous breathing, which is generally considered the most suitable one, partly because significantly greater variability of blood flow velocity appears when the baby is breathing out of synchrony with the ventilator.[2]

In order to accomplish synchronous ventilation and improve ventilator-patient interaction, the ventilator should be, obviously, activated only on patient request, i.e., when a trigger signal is generated by the patient's breathing attempt. Firstly, it was proposed the utilization of sensors, directly applied on the patient, (1) to detect abdomen, chest movements[3,4] or esophageal pressure[5] and (2) to indicate the patient's own respiratory effort. However, the proposed methods to trigger ventilators presented some problems connected to the unreliability due to the recognition of improper signals (for example cough or, more simply, a body movement of the patient), that may cause active expiration against positive pressure inflation. Then, research was focused on pressure-triggered ventilation,[6] performed by detecting the air pressure decrease due to the patient's spontaneous breathing attempt. However, this method could be utilized only with steady breathing patients, i.e., only as a support to spontaneous breathing in weaning phase. It is necessary to outline that in preterm neonatal patients the signal may be too low to properly trigger the ventilator. The previously indicated limitations determined[7–11] the realization of flow-triggered ventilators that are capable to detect flow variation caused by the patient's spontaneous inspiration. Patient's treated with flow-synchronized ventilation are usually weaned more rapidly and have significantly shorter mean time to extubation than those treated with time-cycled pressure-limited ventilator.[12]

The main design constraints of a flow-triggered ventilator can be summarized as follows: (1) a sufficient trigger sensitivity; (2) a reduced delay time, which is mainly composed of two parts: (a) the time interval between the beginning of the patient breathing attempt and (b) the time interval between trigger signal and the opening of gas delivery valve; and (3) finally, their value drift, especially when ventilators are set for neonatal application and the values of the aforementioned performances are very low. Moreover, to prevent the ventilator from being activated by improper trigger signals caused by flow spikes, sometimes, the trigger ventilator system is made sensitive to flow time-integral, i.e., inspirated volume, so that trigger sensitivity value can be expressed in volume units. It is necessary to observe that for preterm neonatal application, the tidal volume could be extremely low ($\cong$5–7 ml/kg[13] as normal term) and, as a consequence, typical trigger values lie in the range of 0.02–3 ml.[14]

Due to the previously indicated low sensitivity value, it is generally difficult to realize: (1) extremely reliable neonatal ventilator capable of assuring high successful triggering rate;[15] (2) neonatal patient simulator with equivalent metrological characteristic. The last mentioned problem is one of the main reasons why response time and trigger reliability are usually tested *in vivo*, as it emerges from the examined literature.[15,16]

Regarding pressure and volume performances and accuracies, several flow-triggered ventilators were investigated using mechanical lung models with selectable resistances and compliances.[17,18] Nevertheless, according to the authors' knowledge, there are no commercially available patient simulators capable of performing the requested neonatal volume and flow values to activate trigger and automatically *in vitro* evaluate response time and reliability of flow-triggered neonatal ventilators. Moreover, the Clinical Engineering Service of the Children's Hospital "Bambino Gesù"* of Rome chose to establish a procedure to carry out an objective and off-site method to compare tests and to evaluate different flow-triggered neonatal ventilators. This exigency emerges both for assuring that only safe, accurate and effective ventilators are brought into the hospital and, also, for properly maintaining these high risk electromedical devices. In consideration of the above exposed reasons, it appeared of inter-

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**The Children's Hospital "Bambino Gesù" (≈730-bed medical facility) is a private and non-profit hospital located in Vatican City, i.e., the independent Papal state within the city of Rome, Italy. The Clinical Engineering Service manages about 3800 pieces of electromedical equipment (35 million US dollars).*

est to develop a system capable of automatically testing the aforementioned ventilator performances.

THE EXPERIMENTAL SETUP

The experimental setup proposed to evaluate and verify response time and reliability of flow-triggered neonatal ventilator parameters may be considered in two main parts controlled by means of a computer: the first part realizes a neonatal patient simulator and the second one is the measuring system. The patient simulator consists in a shaker driven test lung (e.g. bellows) capable of generating little airflows, either positive or negative, depending on the displacement imposed to the shaker diaphragm. To move the shaker, two different power supplies have been utilized; the first, utilized only in the patient simulator calibration procedures, is a power supply whose voltage is manually regulated. The second power supply lies in a power amplifier which amplifies the signal generated by a computer-controlled function generator (Universal Source, US).

With reference to Fig. 1, the system has been calibrated by imposing displacements, measured by means of a linear variable differential transformer (LVDT), to the bellows and by reading the related displacement of a fluid column in a graduated tube. The calibration procedures have been performed three times for positive and negative displacements. The variations of bellows volume as a function of the applied shaker displacements (measured by means of LVDT outputs) are linear (correlation coefficient always >0.99). The sensitivity value is constant in the range from −1 to 1 ml and equal to 1 ml/V, with a standard deviation always <0.01 ml.

Once the patients simulator system has been calibrated, it is connected to the ventilator to test, as illustrated in Fig. 2. From an examination of this figure, it can be observed that a second bellows has been placed in the hose system to simulate patient compliance; the utilized bellows has been chosen from those commonly suggested by ventilator manufacturers. In the test setup, the shaker is controlled by means of the US and the power amplifier; the functions generated by the US can be customized for the particular ventilator trigger system to test. More specifically, by means of the proposed patient simulator system, the Clinical Engineering Service technicians are able to chose the shape of the curve which represents the volume variation as a function of time and to regulate, at the same time, both the temporal flow variation law and its peak level in the most suitable way, in order (1) to trigger the ventilator with an appropriate volume variation and (2) to measure response time. To verify the

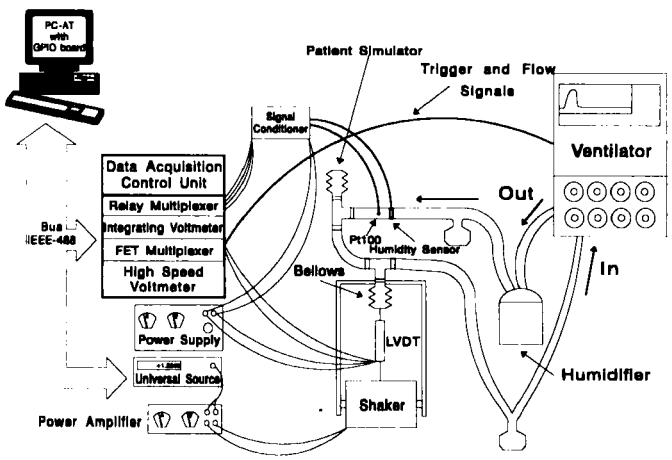


Fig. 1—*Experimental setup used for calibrating patient simulator*

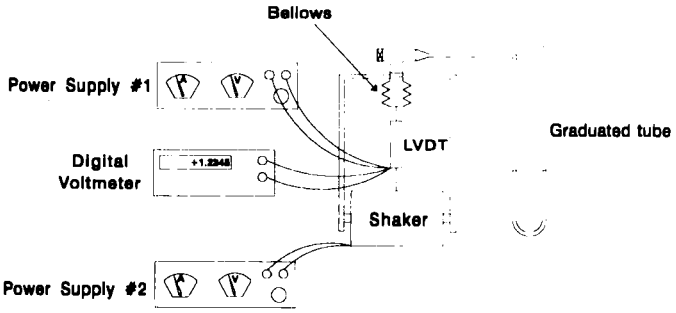
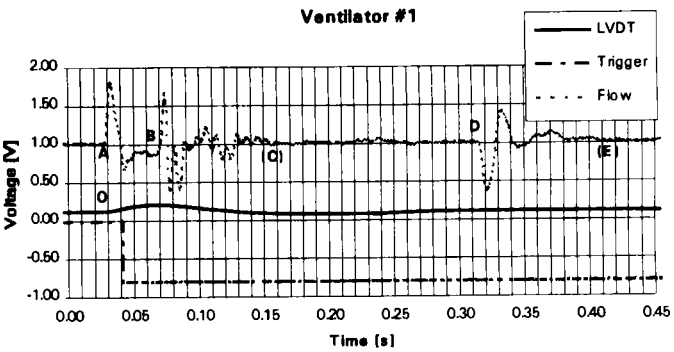


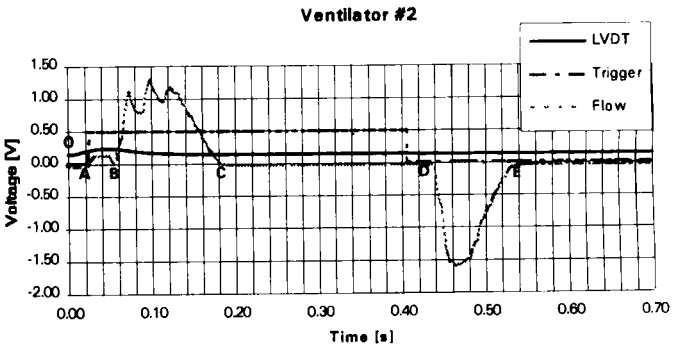
Fig. 2—*Ventilator test setup*

effectiveness of the proposed setup, it was decided to impose volume time variation similar to the physiological one.

The measuring system collects the signals of: (1) LVDT, (2) trigger and (3) flow (where the last two signals are directly picked up from the tested ventilator) by means of a FET multiplexer (FET MUX) implemented inside a data acquisition control unit (DAC), which connects, via backplane, the terminals with a built-in high speed voltmeter (HSV) that allows a scanning speed equal to 10 kHz. Inside the hose system are also placed a temperature and a humidity sensor to monitor gas parameters, whose signals are sent to a relay multiplexer (Relay MUX), internal to the DAC, which is automatically scanned by the DAC itself and the signals are read by an integrating voltmeter (IV) in the DAC. The whole system is controlled by an AT PC with a general purpose interface board (GPIB), by means of a bus IEEE-488. All the data are collected in the PC hard disk to be post-processed in a second phase, in order to show the results in graphic detail.



(a)



(b)

Fig. 3(a) and (b)—*Preliminary test results for ventilator #1 and #2*

TESTS AND RESULTS

To verify the effectiveness of the proposed test system, two neonatal ventilators, from different manufacturers, are comparatively examined. These ventilators, named #1 and #2 for clearness sake, are set in assisted spontaneous breathing mode and triggered by the computer-controlled patient simulator; they are set for maximum allowed trigger sensitivity setting. Both ventilators utilize hot-wire anemometer method to measure gas flow inspired and expired by the patient. Anyway, whereas ventilator #1 utilizes only one anemometer positioned in a derived tube parallel to the main airway to the patient, ventilator #2 utilizes two anemometers directly positioned in the main conduct to determine also flow direction. Furthermore, flow and trigger output signals detected by ventilators are directly picked up from analog circuits for ventilator #1, while, for ventilator #2, the same output signals are collected from a digital-analog converter, implemented in the tested machine which involves, according to the manufacturer, a delay time of about 15 ms, to be taken into account when evaluating response time, between the input signals and the conditioned and D/A converted outputs.

In order to recognize and evaluate flow and trigger waveforms, preliminary tests have been conducted and their results are depicted in Figs. 3(a) and (b) for ventilator #1 and #2, respectively. From an analysis of Fig. 3, it emerges that both flow sensors detect the beginning of volume variation, indicated with O, induced by the ventilator test system during the simulation of the patient breathing attempt (AB phase). As regards to ventilator #1, it is possible to notice that, because of the position of flow measuring system parallel to the main airway to the patient, the output is affected from oscillatory flow phenomenon that causes some unpredictable sensor output signal variations. The phase BC corresponds to the breathing stroke generated by the ventilator; with reference to ventilator #1, the end-inspiration point cannot be easily identified because of the previously indicated oscillatory phenomenon. Finally, the time length indicated with DE represents the expiration phase.

With the aim to determine the response time and to verify the proposed setup attitude to perform drift analysis, three hour time tests have been conducted on both ventilators and results relative to different acquisition time are showed in Figs. 4(a), (b) and (c) for ventilator #1 and in Figs. 5(a), (b) and (c) for ventilator #2. The significant ventilation phases are indicated in these figures with the same notation used for Fig. 3; the trigger activation instant is marked with T. It follows, obviously, that response time can be directly determined on the graph. In particular, time length between: (1) O and A represents the time delay due to the signal conditioning operated by the ventilator; (2) A and T represents the trigger activation time; (3) T and B represents the response time of the machine to the electrical signal of the trigger; (4) A and B represents the total response time of the ventilator.

Figure 5 confirms that the delay time due to the signal conditioners implemented in the ventilator #2 is always about 15 ms, as indicated by the manufacturer. Furthermore, total delay times always lie in the range of 45–47 ms and 35–37 ms for ventilator #1 and #2, respectively.

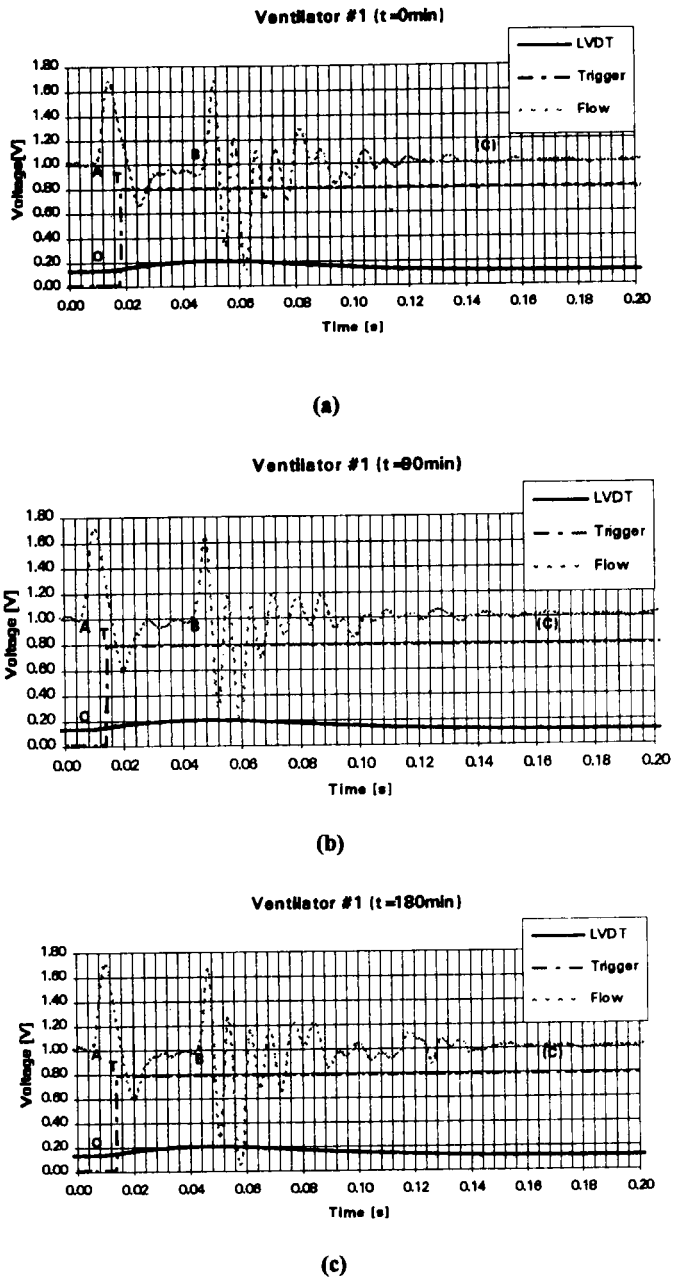


Fig. 4(a), (b) and (c)—*Results relative to different instants of drift test for ventilator #1*

CONCLUSIONS

From the preliminary experimental results, it emerges that the proposed ventilator test system can be effectively utilized either for an objective verification of flow-triggered ventilator performances as a function of time, in order to conduct different machine evaluations, or, during maintenance, for testing working efficiency of these high-risk electromedical devices. Moreover, one of the major benefits of the proposed setup lies in the fact that the ventilator performances can be automatically monitored over a long time period, without requiring the presence of Clinical Engineering Service technicians. In the oncoming research project, the proposed device will be improved by including an automatic system which allows the evaluation of trigger sensitivity, its time-drift and reliability during long-term tests.

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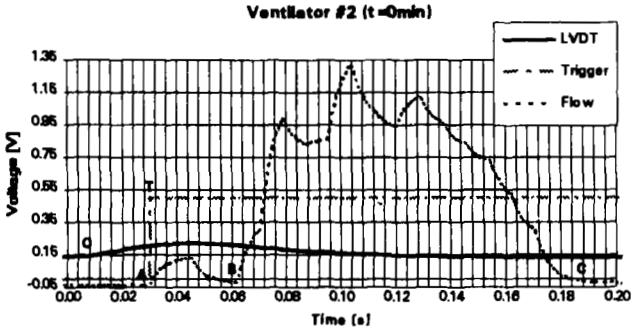
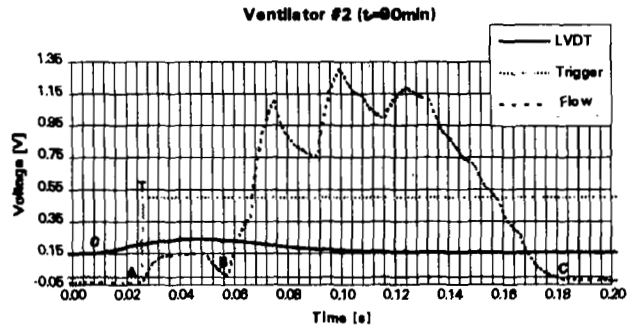


(a)



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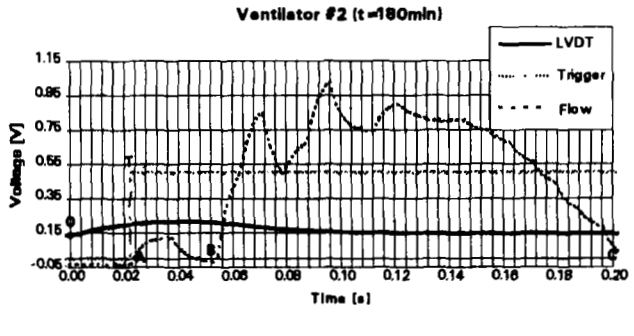

(c)

Fig. 5(a), (b) and (c)—*Results relative to different instants of drift test for ventilator #2*

REFERENCES

1. Greenough, A., Morley, C. and Davis, J., "Interaction of Spontaneous Respiration with Artificial Ventilation in Preterm Babies," J. Pediatr., **103**, *769–773 (1983).*

2. Rennie, J.M., South M. and Morley, C.J., "Cerebral Blood Flow Velocity Variability in Infants Receiving Assisted Ventilation," Arch. Dis. Child., **62**, *1247–1251 (1987).*

3. Metha, A. et al., "Patient Triggered Ventilation in the Newborn," Lancet, **1**, *17–19 (1986).*

4. Heldt, G.P. and McIlroy, M.B., "Distortion of Chest Wall and Work of Diaphragm in Preterm Infants," J. Appl. Physiol., **62**, *164–169 (1987).*

5. Greenough, A. and Grenoll, F., "Patient Triggered Ventilation in the Premature Neonate," Arch. Dis. Child., **63**, *67–68 (1988).*

6. Greenough, A., Hird, M.F. and Chan, V., "Airway Pressure Triggered Ventilation for Preterm Neonates," J. Perinat. Med., **19**, *471–476 (1991).*

7. Mitchell, A., Greenough, A. and Hird, M.F., "Limitations of Patient Trigger Ventilation in Neonates," Arch. Dis. Child., **64**, *924–929 (1989).*

8. Nishimura, M. et al., "Comparison of Inspiratory Work of Breathing Between Flow-triggered and Pressure-triggered Demand Flow Systems in Rabbit," Crit. Care Med., **22**(6), *1002–1009 (1994).*

9. Hird, M.F. and Greenough, A., "Comparison of Triggering Systems for Neonatal Patient Triggered Ventilation," Arch. Dis. Child. **6**, *426–428 (1991).*

10. Hird, M.F. and Greenough, A., "A Patient Triggered Ventilation Using a Flow Triggered System," Arch. Dis. Child., **66**, *1140–1142 (1991).*

11. Greenough, A. and Pool, J., "Neonatal Patient Triggered Ventilation," Arch. Dis. Child., **63**, *394–397 (1988).*

12. Donn, S.M., Nicks, J.J. and Becker, M.A., "Flow-synchronized Ventilation of Preterm Infants with Respiratory Distress Syndrome," J. Perinat. **14**(2), *90–94 (March–April 1994).*

13. Smith, C.A., "Physiology of the Newborn," Charles C Thomas, Springfield, IL, 327 (1959).

14. Dräger, Babylog 8000—Intensive Care Ventilator for Neonatal-User Manual, Germany, 88 (1993).

15. Bernstein G, et al., "Response Time and Reliability of Three Neonatal Patient-triggered Ventilators," Amer. Rev. Respir. Dis., **148**, *358–364 (1993).*

16. Mizuno, K. et al., "Efficacy of Synchronized IMV on Weaning Neonates from the Ventilator," Acta Paediatr. Japan, **36**(2), *162–166 (1994).*

17. Ghaly, J. and Smith, A.L., "Automated Ventilator Testing," Australas Phys. Eng. Sci. Med., **17**(2), *91–93 (1994).*

18. Hauschild, M., Schmalisch, G. and Wauer, R.R., "Measuring Accuracy of Commercial Respiratory Function Equipment and Ventilation Monitors for Newborn Infants," Klin. Padiatr., **206**(3), *167–174 (in German) (1994).*