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## Assessment of neonatal ventilator performances

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**Abstract** *Objective:* To analyze efficiency and reliability of 4 modern neonatal ventilators under difficult test conditions. The ventilators tested were: Babylog 8000 (Dräger Medical), BP 2001 (Bear Medical Systems), Sechrist IV 100 B (Sechrist Industries), Infant Star (Infrasonics INC).

*Measurements and results:* Gas flow generation was tested by comparison of preset flow values with no resistance in the circuit to flow values obtained during interposition of a resistance in the inspiratory circuit. A decrease in gas flow was observed when interposition of a resistance in the inspiratory circuit increased peak inspiratory pressure to 60 cmH<sub>2</sub>O (gas flow decreased by 8% to 24% depending on the ventilator tested). The pressure limiting valve and the positive end-ex-

piratory pressure valve were also evaluated in order to test their behaviour under different flow conditions. Flow-dependence of the pressure was noted for all ventilators except Babylog 8000. Assessment of the reliability of pressure monitoring revealed either 'under' or 'over' estimation of peak inspiratory pressure and positive end-expiratory pressure depending on the ventilator tested.

*Conclusion:* For the best clinical use of mechanical ventilators, neonatologists should be aware of these limitations. Therefore a regular assessment of ventilator performance and monitoring reliability is recommended.

**Key words** Artificial ventilation · Pediatric intensive care · Positive end-expiratory pressure

### Introduction

Mechanical ventilators can be classified as "pressure generators" or "flow generators". In a ventilator that generates pressure, the pressure pattern is imposed whereas the flow pattern depends upon the mechanical properties of the respiratory system.

Whereas a ventilator that generates flow is designed to maintain the set flow pattern even in the event of an acute change in respiratory system impedance. Neonatologists use ventilators that are "flow generators" transformed into pressure limited, constant flow, timecycled ventilators. As the Peak Inspiratory Pressure (PIP) limit is reached,

a valve partially opens allowing gas to escape into the atmosphere in order to maintain the desired PIP level. The quality of the pressure generated is therefore dependent on both the flow generation and the behaviour of the pressure limiting valve.

In order to ensure an optimal efficiency of the mechanical ventilation, the physical characteristics of the patient's lungs should have a minimal effect on the behaviour of the ventilator. However variable ventilator behaviour has been observed with compliance and/or resistance changes in the respiratory system [1–4]. This variation in the ventilator behaviour could be ascribed to differences in ventilator design.

In this study, four neonatal ventilators, which have recently become commercially available, were evaluated. In order to analyze their efficiency and reliability under difficult test conditions, a bench evaluation of the mechanical performance was performed assessing: flow capabilities, pressure control (positive end-expiratory pressure and PIP) and accuracy of the monitoring devices.

## Materials and methods

The study was performed on four different ventilators. In each case a ventilator which had been checked by the company was used. The four neonatal ventilators tested were: Babylog 8000 (Dräger Medical, Lübeck, Germany), BP 2001 (Bear Medical Systems, Riverside, USA), Infant Star (Infrasonics INC, San Diego, USA), Sechrist IV 100 B (Sechrist Industries, Anaheim, USA).

In these ventilators, three main parameters are controlled: peak inspiratory pressure (PIP), positive end-expiratory pressure (PEEP) and gas flowrate (Fig. 1). The characteristics of the ventilators are: Babylog 8000 (Dräger Medical, Lübeck, Germany) delivers flowrate from 1 to  $30 \text{ l} \cdot \text{min}^{-1}$ , PIP from 10 to  $80 \text{ cmH}_2\text{O}$ , PEEP from 0 to  $15 \text{ cmH}_2\text{O}$ . All these parameters are displayed numerically. BP 2001 (Bear Medical Systems, Riverside, USA) delivers flowrate from 3 to  $30 \text{ l} \cdot \text{min}^{-1}$ , PIP from 0 to  $72 \text{ cmH}_2\text{O}$ , PEEP from  $-2$  to  $20 \text{ cmH}_2\text{O}$ . The pressure monitoring device consists of a mechanical pressure transducer. Infant Star (Infrasonics INC, San Diego, USA) delivers flowrate from 4 to  $40 \text{ l} \cdot \text{min}^{-1}$ , PIP from 8 to  $90 \text{ cmH}_2\text{O}$ , PEEP from 0 to  $24 \text{ cmH}_2\text{O}$ . All these parameters are displayed numerically. Sechrist IV 100 B (Sechrist Industries, Anaheim, USA) delivers flowrate from 0 to  $32 \text{ l} \cdot \text{min}^{-1}$ , PIP from 5 to  $70 \text{ cmH}_2\text{O}$ , PEEP from  $-2$  to  $20 \text{ cmH}_2\text{O}$ . The pressure monitoring device consists of a mechanical pressure transducer.

These three parameters (gas flowrate, PIP, PEEP) were tested in situations simulating 'difficult-to-ventilate' patients. The reliability of the pressure monitoring and fraction of inspired oxygen ( $\text{FIO}_2$ ) settings were also tested.

### Flow generation

In the first part of the study, ventilator flow generation was evaluated to investigate the ability of the ventilator to maintain gas flow under difficult conditions such as high respiratory impedance. To assess the performance of the ventilator, the delivered flowrate was

measured while the ventilator was connected to a variable resistance placed on the inspiratory line (Fig. 1), as proposed by PESLIN [5]. The resistance was progressively increased in order to simulate abnormalities in the respiratory system. This resulted in inspiratory pressures of up to  $60 \text{ cmH}_2\text{O}$ . During these measurements the pressure limiting valve was closed, in order to avoid any leak and PEEP valve open.

Flow and pressure were measured 'upstream' to the added resistance. The circuit downstream of the resistance was open to atmosphere. As the resistance was increased resulting in an increase in pressure, any decrease in flow corresponded to a power limitation of the mechanical ventilator. The performance of the ventilator was therefore expressed as a flow-pressure curve.

The experiments were repeated for three different flow conditions – ventilator flowrates set at 5, 10 and  $20 \text{ l} \cdot \text{min}^{-1}$ . To achieve the whole range of pressures for different flows, the resistance had to be increased from  $30 \text{ cmH}_2\text{O} \cdot \text{l}^{-1} \cdot \text{s}^{-1}$  (pressure equal to  $10 \text{ cmH}_2\text{O}$  for a flow set at  $20 \text{ l} \cdot \text{min}^{-1}$ ) to  $720 \text{ cmH}_2\text{O} \cdot \text{l}^{-1} \cdot \text{s}^{-1}$  (pressure equal to  $60 \text{ cmH}_2\text{O}$  for a flow set at  $5 \text{ l} \cdot \text{min}^{-1}$ ).

In order to test whether the behaviour of the ventilator was identical at low and high frequencies, two flow-pressure curves were plotted for each selected flowrate, one with the respiratory frequency set at 40 bpm and one with the respiratory frequency set at 100 bpm. In each case the I:E ratio was kept constant on a ratio of 1:2.

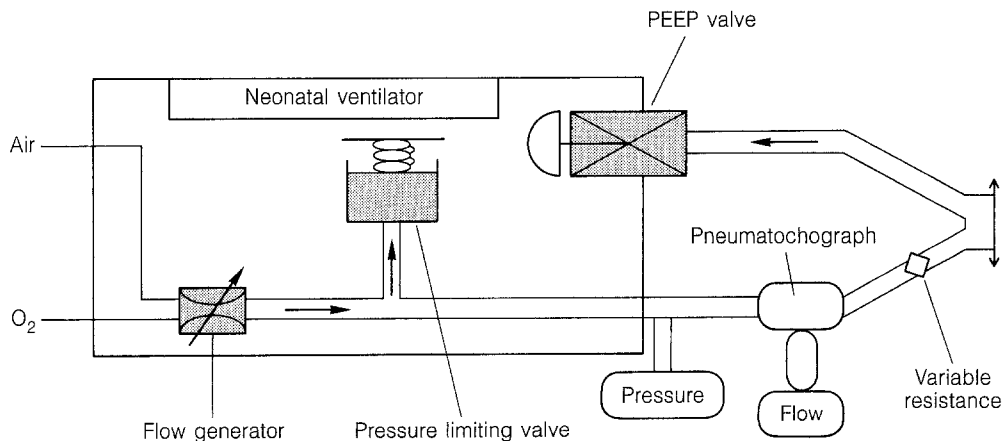
Inspiratory pressure was measured with a Validyne MP45  $\pm$   $140 \text{ cmH}_2\text{O}$  differential pressure transducer (Validyne Corp., Northridge, CA). Inspiratory flow was measured with a heated Fleisch #0 pneumotachograph connected to a Validyne MP45  $\pm$   $2.5 \text{ cmH}_2\text{O}$  differential pressure transducer. We have verified the linearity of the Fleisch pneumotachograph in the range of flow  $0$ – $20 \text{ l} \cdot \text{min}^{-1}$ . Airflow was integrated for measurement of tidal volume. All signals were recorded on a Gould recorder TA 550. All ventilators were studied with the same breathing circuit tubing (80 cm long, 10 mm internal diameter and  $0.35 \text{ ml} \cdot \text{cmH}_2\text{O}^{-1}$  compliance), which was tested for the absence of leaks.

### Flow dependence of the pressure valves

To test the behaviour of the pressure limiting valve (PIP valve), the Y piece was completely obstructed, then ventilator gas flow was sequentially increased from 3 to  $20 \text{ l} \cdot \text{min}^{-1}$ .

Using this method, it was possible to increase the flow passing through the valve for a given pressure limiting valve position. As flowrates passing through the valve were increased, corresponding variations in PIP were recorded.

**Fig. 1** Schematic diagram of the three main components of a neonatal ventilator: flow generator, pressure limiting valve and positive end expiratory pressure (PEEP) valve. Such a ventilator behaves as a pressure-limited, constant flow, time-cycled ventilator



Measurements were recorded for three different valve positions corresponding approximately to 20, 40 and 60 cmH<sub>2</sub>O. The test was performed using two different respiratory frequencies: 40 and 100 bpm. In each case the I:E ratio was kept constant at 1:2 and no PEEP was added.

To test the PEEP valve, the same method was used as for the pressure limiting valve, above except that the ventilator was set in the continuous positive airway pressure (CPAP) mode. In the CPAP mode, gas continuously flows through the breathing circuit and passes through the PEEP valve. Theoretically, the PEEP valve should maintain a constant pressure regardless of the set flowrate. Four different levels of PEEP were evaluated using four different positions of the PEEP knob on the ventilator. The PEEP knob positions were obtained by dividing the PEEP scale into equal ranges: minimum PEEP, 1/3 of maximum PEEP, 2/3 of maximum PEEP and maximum PEEP. For each of these PEEP settings, the ventilator flowrate was increased from 3 to 20 l·min<sup>-1</sup>.

#### Monitoring test

To evaluate the reliability of the ventilator monitoring, set values for PIP, PEEP and FIO<sub>2</sub> displayed on the front panel of the ventilator were compared with the same values simultaneously measured by an independent method. No interobserver errors were tested. PIP and PEEP values used were obtained from data gathered during evaluation of flow generation of the ventilators. FIO<sub>2</sub> monitoring was assessed by setting ventilator FIO<sub>2</sub> on 21%, 25%, 30%, 50% and 75% respectively. Samples of inspiratory gas were taken with a 50 ml syringe and analyzed in duplicate with a blood gas analyzer ABL 30 (Radiometer, Copenhagen, Denmark). The results have been presented as an error ratio percentage: 100 × (measured value – value read on the ventilator)/measured value.

## Results and discussion

### Flow generation

In the 'usual' conditions of mechanical ventilation (PIP between 10 to 30 cmH<sub>2</sub>O), the tested ventilators were able to maintain a constant flow even during situations simulating a 'difficult-to-ventilate patient' with high respiratory impedance 'downstream' to the flow measurement. For flow settings of 5, 10 and 20 l·min<sup>-1</sup> and pressures of up to 40 cmH<sub>2</sub>O, all ventilators tested behaved

**Table 1** Changes in flow generated by the ventilator at different levels of pressure in the breathing circuit. Results are expressed as a percent changes from the flowrate measured at a pressure of 10 cmH<sub>2</sub>O in the breathing circuit.

| Breathing circuit pressure | Flow setting (l·min <sup>-1</sup> ) | BBL 8000 | BP 2001 | Infant star | Sechrist |
|----------------------------|-------------------------------------|----------|---------|-------------|----------|
| 40 cmH <sub>2</sub> O      | 5                                   | -6%      | -12%    | -6%         | -17%     |
|                            | 10                                  | -4%      | -8%     | -6%         | -13%     |
|                            | 20                                  | -4%      | -6%     | -4%         | -8%      |
| 60 cmH <sub>2</sub> O      | 5                                   | -15%     | -22%    | -12%        | -29%     |
|                            | 10                                  | -8%      | -12%    | -9%         | -18%     |
|                            | 20                                  | -5%      | -8%     | -7%         | -17%     |

satisfactorily, with the Sechrist ventilator showing the larger decrease in flow (Table 1).

When the pressure was increased to 60 cmH<sub>2</sub>O, ventilator performance remained satisfactory for flow settings of 10 and 20 l·min<sup>-1</sup>. However for the lower flow setting of 5 l·min<sup>-1</sup>, a marked decrease in flow was observed: compared to the value measured under low pressure conditions, the flow measured on the Sechrist ventilator decreased by 29% (Table 1).

When the respiratory frequency was increased from 40 to 100 bpm there was no change in the flow measured, indicating that set frequency had no effect on the flow generation (data not shown).

In conclusion the results suggest that the flow generators in the four neonatal ventilators tested can be considered as highly powerful within the clinical pressure range (0–40 cmH<sub>2</sub>O). However for low flow settings and high pressures, the reliability of the flow generators appears to be reduced.

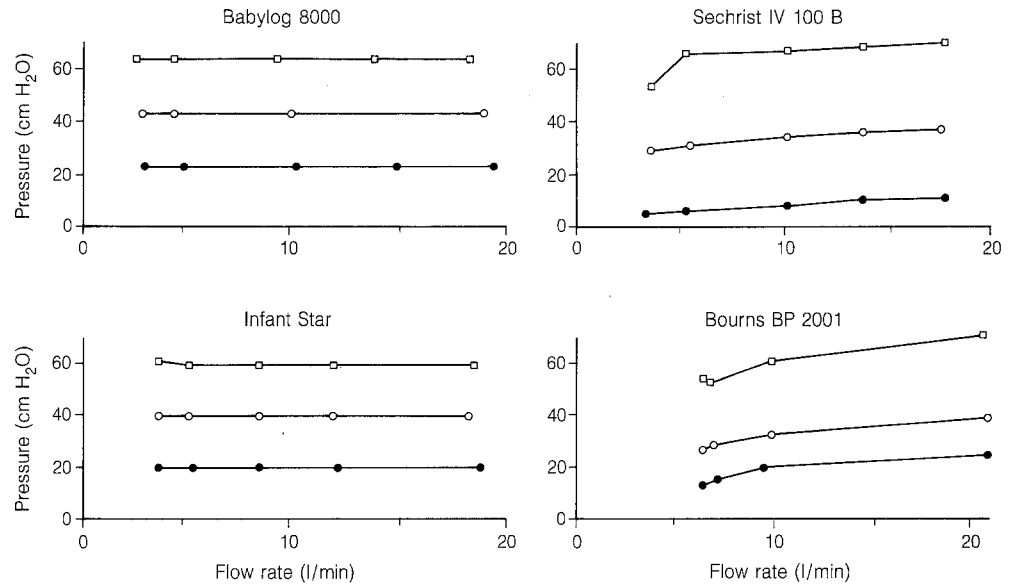
### Flow dependence of the pressure valves

An ideal pressure valve should achieve an 'upstream' pressure independently from the gas flowrate passing through the valve.

Peak inspiratory pressure is controlled by the pressure limiting valve which releases gas from the system whenever the pressure in the breathing circuit rises above the set value. Performance of the pressure limiting valve was excellent in two of the ventilators tested. Regardless of the flowrate, the pressure limiting valve maintained a constant pressure (change < 3%) in the Babylog 8000 and the Infant Star ventilators. A large pressure-gas flow dependency was noted in the other two ventilators and was even larger at high frequencies (Fig. 2, Table 2).

Pressure control is an important concern for paediatric intensivists as the risk of barotrauma is high in newborns due to their weak lungs. Risks not only include intrathoracic gas leak but also intraventricular haemorrhage and broncho-pulmonary dysplasia [6, 7]. Inspiratory pressure is controlled by the pressure limiting valve which can exhibit a flow resistance suggestive of an increase in pressure when the gas flowrate through the valve increases. PIP-gas flow independency has obvious clinical advantages: ventilation is more easily adjusted (when the gas flow setting on the ventilator is modified, there is no need to change the setting of PIP valve) and excess pressure is avoided in situations which increase the flow through the valve such as partial obstruction of the endotracheal tube. It must be noted above results were obtained using a static test. The risk of 'pressure overshoot' may be even more critical in clinical practice and under dynamic test situations. Simulation of active expiration such as coughing during ventilation insufflation could provide further information [8].

**Fig. 2** Test of the pressure limiting valve. Changes in peak inspiratory pressure of 4 neonatal ventilators according to the flow increase in the breathing circuit for three given valve positions (Y piece obstructed), Respirator frequency = 40 bpm, I : E = 1/2



The same arguments apply to PEEP-gas flow interdependency. Reliable adjustment of PEEP is critical in the management of newborns and any variation from the optimal PEEP could induce a barotrauma and impair the hyperpneic or weaning phases [9]. During the expiratory phase the flow passing through the PEEP valve is the sum of the expiratory flow from the patient and the continuous flow delivered by the ventilator. Since a flow resistance of the PEEP valve occurs, the same PEEP setting induce a PEEP increase when the flow rate through the valve increased.

The PEEP-gas flow dependency was minimal in the Babylog 8000 and Infant Star ventilators for gas flowrates of 5 and 10 l·min<sup>-1</sup> (Fig. 3). In contrast however both the BP 2001 and Sechrist ventilators displayed a large increase in PEEP when the flow through the valve increased (Fig. 3).

The results of this study show that some modern neonatal ventilators have reached a high standard of performance with regard to pressure valves and pressure-gas flow independence. These performances can be attributed to the optimal valve design and/or servo-control mechanism modifying the flow to maintain the pressure.

This improvement in design has clear benefits when

considering the greater simplicity in setting pressures that are independent of the set flowrate.

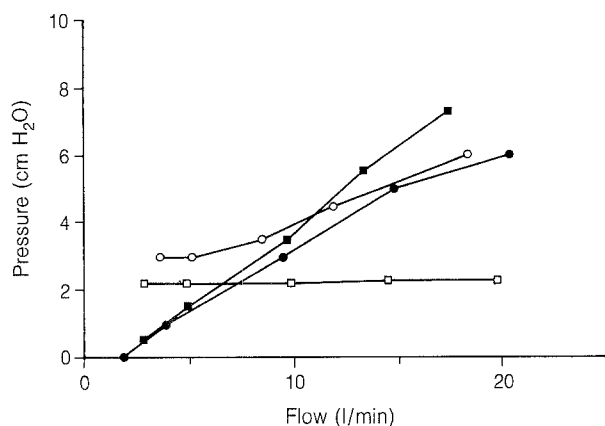
#### Monitoring

All ventilators only slightly underestimated FIO<sub>2</sub> with an error < 3% in the 21 to 30% range and an error of < 5% for FIO<sub>2</sub> greater than or equal to 30% (Table 3). This error is mainly due in low FIO<sub>2</sub> range to the lack of decimal point on settings value compared to blood gas analyzer value. Hyperoxia could damage the retina in premature babies even with low settings of FIO<sub>2</sub> [10], therefore FIO<sub>2</sub> has to be precisely controlled. All ventilators performed satisfactorily in monitoring FIO<sub>2</sub>.

Some inaccuracies were observed in the pressure display: PIP and PEEP were underestimated in the BP 2001 and overestimated in the Sechrist and Babylog 8000 (Fig. 4). The imprecision in pressure readings documented in this study may be related to three major causes [11]. Firstly, on one of the ventilators, the pressure monitoring device consists of a mechanical pressure transducer which is read by visual observation. This may lead to observer related reading errors. Secondly, no mechanical calibration

**Table 2** Peak inspiratory pressure maximum variation ( $\Delta P$ ) resulting from a flow increase from 5 to 20 l·min<sup>-1</sup> in the breathing circuit for a given valve position (Y piece obstructed). Results compare two ventilator frequencies 40 and 100 bpm using the same I : E ratio of 1 : 2.

|         | Babylog 8000<br>$\Delta P$ (cmH <sub>2</sub> O) | BP 2001<br>$\Delta P$ (cmH <sub>2</sub> O) | Infant Star<br>$\Delta P$ (cmH <sub>2</sub> O) | Sechrist<br>$\Delta P$ (cmH <sub>2</sub> O) |
|---------|---|--|--|---|
| 40 bpm  | 0   | 7  | 0  | 6   |
| 100 bpm | 0   | 21.5                                       | 0  | 28  |



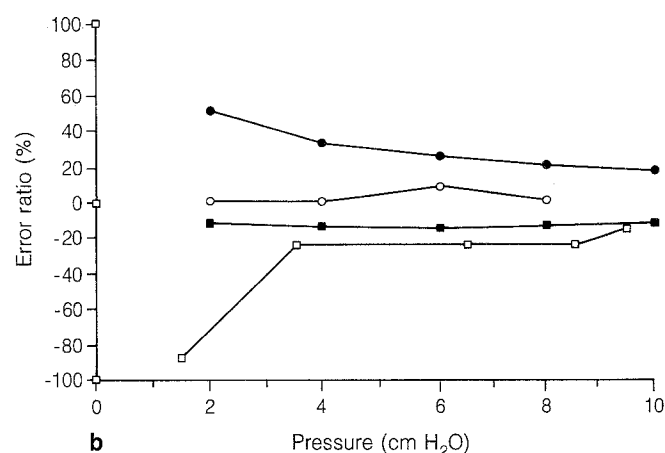
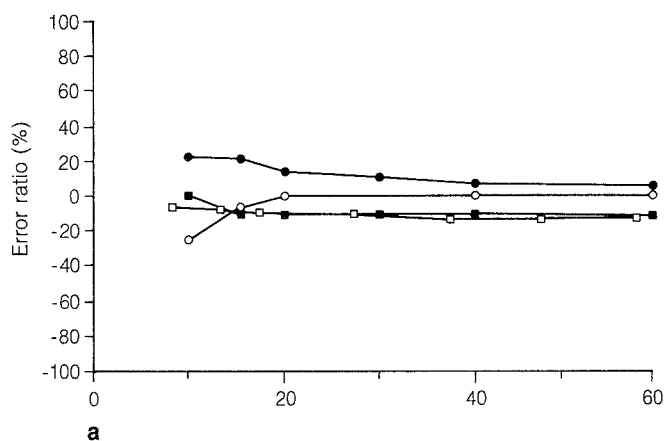
**Fig. 3** Test of the PEEP valve. Changes in positive end expiratory pressure (PEEP) of the neonatal ventilators studied according to the flow in the breathing circuit: the ventilator is set in the CPAP mode with the Y piece obstructed. —□— Babylog 8000, —●— BP 2001, —■— Sechrist, —○— Infant Star

**Table 3** FIO<sub>2</sub> set on the neonatal ventilator compared to FIO<sub>2</sub> measured with an independent gas analyzer ABL 30 (Radiometer, Copenhagen). FIO<sub>2</sub> are in percent. The differences between prescribed FIO<sub>2</sub> and measured FIO<sub>2</sub> are below 5%.

| FIO <sub>2</sub> prescribed | BBL 8000 | BP 2001 | Infant Star | Sechrist |
|-----------------------------|----------|---------|-------------|----------|
| 21                          | 21.6     | 21.5    | 21.7        | 21.8     |
| 25                          | 25.1     | 26.8    | 25.7        | 24.7     |
| 30                          | 30.6     | 31.7    | 31.0        | 30.6     |
| 50                          | 52.4     | 52.5    | 51.8        | 51.6     |
| 75                          | 78.8     | 77.3    | 77.3        | 76.8     |

procedure is possible other than a zero adjustment. Thirdly, the pressure measurement was made in the breathing circuit distal to the point at which the ventilator measured its pressures. Differences of 2–3 cmH<sub>2</sub>O between these pressure measurements have been reported and may be caused by gas compression and dynamic characteristics of the systems. Whatever the precise cause may be, it must be noted that significant differences between the PEEP level indicated by the ventilator and the actual PEEP level applied to the patient can be observed.

In conclusion, this study was designed to investigate the performance of newly available neonatal ventilators in the event of an acute change in the mechanical properties of the respiratory system. For the best clinical use of mechanical ventilators, neonatologists should be aware of these limitations. In addition, the monitoring reliability



**Fig. 4a** Reliability of the peak inspiratory pressure (PIP) monitoring for the 4 neonatal ventilators studied based on the differences between the PIP value read on the ventilator (*PIPr*) and the PIP value measured in the breathing circuit (*PIPm*). On the *horizontal axis*: *PIPm*, on the *vertical axis*: error ratio (%) =  $100 \times (PIPr - PIPm) / PIPm$ . **b** Reliability of the positive end expiratory pressure (PEEP) monitoring for the 4 neonatal ventilators studied based on the differences between the PEEP value read on the ventilator (*PEEPPr*) and the PEEP value measured in the breathing circuit (*PEEPm*). On the *horizontal axis*: *PEEPm*, on the *vertical axis*: error ratio (%) =  $100 \times (PEEPPr - PEEPm) / PEEPm$ . —■— Babylog 8000, —●— BP 2001, —□— Sechrist, —○— Infant Star

should be checked regularly to determine its long term quality.

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