

V. Nève
R. Cremer
F. Leclerc
R. Logier
A. Sadik
L. Storme
A. Martinot
Y. Riou
B. Grandbastien

Measurement of respiratory mechanics in paediatric intensive care: in vitro assessment of a pulmonary function device

Received: 18 November 1997
Accepted: 20 May 1998

This work was supported by grants from the Commission Mixte de la Recherche du CH et U de Lille (Projet Micronat/Arcas, contrat 9301). The monitoring system, Eolia, is the result of a partnership between the CH et U de Lille and Dufour S. A. and was manufactured by Dufour S. A., 24 rue de la Tradition, 59653 Villeneuve d'Asq, France

V. Nève · R. Cremer · F. Leclerc (✉) ·
A. Sadik · L. Storme · A. Martinot
Services de Réanimation Pédiatrique
et de Néonatalogie, Centre Hospitalier
et Universitaire de Lille, 2 avenue Oscar
Lambret, 59037 Lille Cedex, France
Tel.: + 33 (3) 20 44 60 93
Fax: + 33 (3) 20 44 61 33

R. Logier
Institut de Technologie Médicale, CH et U
de Lille, 2 avenue Oscar Lambret,
59037 Lille Cedex, France

Y. Riou
Service d'Explorations Fonctionnelles
Respiratoires, CH et U de Lille, 2 avenue
Oscar Lambret, 59037 Lille Cedex, France

B. Grandbastien
Service d'Epidémiologie et de Santé
Publique, Hôpital Calmette, CH et U
de Lille, 2 avenue Oscar Lambret,
59037 Lille Cedex, France

Abstract *Objective:* To evaluate a recently developed and manufactured device for monitoring respiratory parameters in mechanically ventilated children.

Design: In vitro study using a lung model.

Setting: University paediatric intensive care unit.

Material and interventions: Evaluation of the accuracy of volume and pressure measurements, of the determination of respiratory system compliance (10 to 30 ml/cmH₂O) and of resistance (20 and 50 cmH₂O/l per s) by the inflation technique (volume- and pressure-controlled mode of ventilation); assessment of interobserver agreement for compliance (10, 15 ml/cmH₂O) and resistance (20, 50 cmH₂O/l per s) determinations (ANOVA, intraclass correlation coefficient).

Measurements and results: The accuracy of volume measurements (No. 1 Fleisch pneumotachograph) was $\leq 5\%$ of true volumes up to 1 l (Flow: 30 l/min) even after the introduction of an endotracheal tube. The accuracy of pressure measurements up to 70 cmH₂O was $\leq 2.5\%$ of the true values. Coefficients of variation of volume and pressure measurements were $< 2\%$. The accuracy of compliance and resistance

determinations was, respectively, ≤ 17 and 25% of the true values. No significant observer effect was found on compliance and resistance determinations. Indeed, mean differences in compliance and resistance determinations by pairs of observers were $< 1\%$. Intraclass correlation coefficients were > 0.98 .

Conclusions: The measuring error of volume, pressure, compliance and resistance determined using this monitoring system seems acceptable for monitoring purpose. Moreover, use of this system by members of the medical team can be recommended since results obtained by observers, even untrained ones, were similar. In vivo evaluation is now needed.

Key words Respiratory mechanics · Monitor assessment · Accuracy · Interobserver agreement · Ventilated child

Introduction

Monitoring techniques of respiratory function are used increasingly in paediatric intensive care units. Different methods of carrying out lung function tests in ventilated children are known and several commercial devices are available. However, the frequent lack of studies describing the properties of the equipment and the accuracy of these commercial devices have delayed the general acceptance of these techniques in paediatrics.

A portable computerised device for bedside monitoring of respiratory parameters in mechanically ventilated children has been developed and manufactured (Eolia, Dufour, Villeneuve d'Asq, France) [1, 2]. The device investigated is independent of the ventilator and records flow and pressure at the airway opening. After insertion of the pneumotachograph, it allows the determination of pulmonary mechanics during inflation by the ventilator without occlusion or disconnection from the ventilator. Respiratory system resistance ($R_{rs, infl.}$) and compliance ($C_{rs, infl.}$) are well correlated to values measured by the occlusion method [3, 4]. However, the accuracy of the volume and pressure measurements has not been described, the validity of the calculation of respiratory mechanics has not been assessed against a lung model and the agreement of $R_{rs, infl.}$ and $C_{rs, infl.}$ determination by various, possibly inexperienced, observers has not been demonstrated. Indeed this agreement must be assessed since this device has been designed for monitoring purposes, which involves handling by more or less trained users. Therefore the aims of the study were to evaluate the accuracy of volume and pressure measuring systems, to validate in vitro the determination of respiratory mechanics by the inflation technique comparing the $R_{rs, infl.}$ and $C_{rs, infl.}$ determined by the monitoring system to the known resistance and compliance of a lung model and to assess the agreement of $R_{rs, infl.}$ and $C_{rs, infl.}$ determinations between observers.

Materials and methods

Volume and pressure measuring devices

Flows were obtained by a grid Fleisch pneumotachograph, either a No. 0 (dead space 4.7 ml) or a No. 1 (dead space 15 ml). The pneumotachograph had a pressure port on each side of the capillary tube and was connected to a piezoelectric differential pressure transducer (± 12.7 cmH₂O, 163PC01D36, Honeywell, USA) whose sensitivity was reduced to ± 2 cmH₂O by analogue amplifiers (TL 074 type, Texas Instruments, Dallas, Tex., USA), mounted to get variable offset and gain. A first-order filter, with a cut-off frequency at 100 Hz was added to the amplifier as an anti-aliasing filter to reduce the signal-noise ratio. Volume variations were obtained by numerical integration of flow. Pressure measurements were performed using a third pressure port, placed just proximal to the pneumotachograph, and connected to a piezoelectric pres-

sure transducer (± 70.3 cmH₂O, 162PC01D, Honeywell, USA). Flow and pressure signals were digitised at 256 Hz and synchronised with 0.0625° phase shift at 10 Hz (17.36 μ s relative delay). Signals were "smoothed" using a second-order numerical filter. The volume channel was calibrated using a calibrated syringe (Hans Rudolph, Kansas City, Mo., USA). The pressure channel was calibrated using an electronic manometer (Pic 400 Premier, Metrathec, UK).

Lung model

A lung model (VT2, Bio-Tek Instruments, Winooski, Vt., USA) allowed the setting of various levels of resistance and compliance. The airway of the lung model was simulated by plug-in calibrated linear resistors (Hans Rudolph 710–508 and 710–369, Kansas City, Mo., USA). The accuracy of the resistor of 20 cmH₂O/l per s was 5% up to 60 l/min and the accuracy of the resistor of 50 cmH₂O/l per s was 2% up to 30 l/min. Thoracic and lung compliance were simulated by a precision alloy steel spring, which was stretched by the rise of the lung top plate. Compliance adjustment was achieved by positioning of spring relative to the hinge point of the top plate. Actual compliance could be set by positioning the spring against a calibrated scale (from 10 up to 150 ml/cmH₂O). The accuracy of the lung model compliance was $\pm 2\%$. The pneumotachograph was inserted in series between the ventilator circuit (Siemens Servo 300, Solna, Sweden) and the lung model. The lung model was ventilated with air coming out of the wall outlet with a fractional inspired oxygen (FIO₂) of 21%. The heat and moisture exchanger was disconnected following the recommendations of the manufacturer of the lung model.

Method of calculation of $C_{rs, infl.}$ and $R_{rs, infl.}$

Tidal flow, volume and pressure at the airway opening were recorded during mechanical ventilation. On the monitor, the observer froze flow-volume and volume-pressure loops. Immediately after the loops were frozen, as is usually done for bedside measurements, measurement of $R_{rs, infl.}$ and $C_{rs, infl.}$ by the observer was determined off-line by the positioning of cursors to determine slopes on the frozen loops. This enabled us to achieve a greater accuracy in the positioning of the cursors.

In the volume-controlled mode [3], the relationship between driving pressure and inspiratory volume was a linear function of the type $a + bx$, in which the slope (b) was $1/C_{rs, infl.}$, and the intercept on the pressure axis (a) provided $Pres + PEEP_{rs, infl.}$. Pres was the total resistive pressure, $PEEP_{rs, infl.}$ the total positive end-expiratory pressure calculated as follows:

$$PEEP_{rs, infl.} = PEEP_v + PEEP_{i, infl.}$$

where $PEEP_v$ was the PEEP applied by the ventilator and $PEEP_{i, infl.}$ the intrinsic PEEP calculated from flow-volume loops:

$$PEEP_{i, infl.} = (V_e - V_t) / C_{rs, infl.}$$

where $(V_e - V_t) = V_{trap}$, volume of trapped gas, V_t expiratory tidal volume during mechanical ventilation calculated from integration of expiratory flow and V_e expiratory volume on the completion of passive expiration calculated from extrapolation of the slope of the linear portion of the expiratory loop up to zero flow level. Thus:

$$Pres = a - PEEP_{rs, infl.}$$

$$R_{rs, infl.} = (Pres / \dot{V}_i)$$

where the constant inspiratory flow (\dot{V}_i) was determined by cursors on the flow-volume loop.

In the pressure-controlled mode [4],

$$\text{Crs, infl.} = (V_T + V_{\text{trap}}) / (\text{Pao} - \text{PEEPv})$$

where V_i was obtained by integration of inflatory flow and V_{trap} from the slope as described for the volume-controlled mode. Pao was the constant inflation pressure applied by the ventilator. Rrs, infl. was obtained from the analysis of the inflatory part of the flow-volume loop. As Pao was constant [and equal to peak inspiratory pressure (PIP)], the relationship between inflatory volume and flow was a linear function of the type $y = a + bx$, in which the slope (b) defined the inflatory time constant of the respiratory system ($\text{Rrs, infl.} \times \text{Crs, infl.}$). The slope was determined on the linear inflatory part of the flow-volume loop. Thus

$$\text{Rrs, infl.} = b / \text{Crs, infl.}$$

Accuracy of the volume and pressure measuring devices

The accuracy of the volume measuring device was determined by injecting manually at a rate of 30 cycles/min volumes over the range of 20 to 400 ml through a No.0 pneumotachograph and over the range of 50 to 1000 ml through a No.1 pneumotachograph using either a 100-ml or a 1000-ml calibrated syringe. In addition, accuracy was evaluated when pneumotachographs were connected to a 3.5-mm Portex tracheal tube. The accuracy of the airway pressure measuring apparatus was determined by applying pressures over the range of 2 to 70 cmH₂O using an electronic manometer. Five measurements were repeated for every level of volume or pressure. Known values were compared to measured values calculated by the monitoring system [2] and results are expressed as accuracy [(ratio of maximal difference between known and measured values to known value) \times 100] and coefficient of variation (CV) in per cent [ratio of standard deviation (SD) to mean].

Accuracy of Rrs, infl. and Crs, infl. measurements

For Rrs, infl. and Crs, infl. measurements, flow-volume and volume-pressure loops were obtained using resistors of 20 or 50 cmH₂O/l per s and four lung model compliance levels (10, 15, 20, 30 ml/cmH₂O). The loops were recorded in duplicate, in volume-controlled and pressure-controlled mode, with the following ventilator settings: expiratory flow 2.8 l/min, respiratory rate (RR) 20 breaths/min, PEEP 10 cmH₂O, mean inspiratory time 48% (SD 15%). Values measured by the monitoring system are presented in the tables as mean (SD) of four values for Crs, infl. measurements and of eight values for Rrs, infl. measurements and in the text as range (% of known value) and CV.

Assessment of agreement of Rrs, infl. and Crs, infl. measurements among three observers

Flow-volume and volume-pressure loops were obtained using the model resistance of 20 or 50 cmH₂O/l per s, model compliance of 10 or 15 ml/cmH₂O and ventilating the model either in volume-controlled or in pressure-controlled mode. Ventilator settings were in volume-controlled mode: expiratory flow 2.5, 3.7 or 5 l/min, RR 20/min, PEEP 10 cmH₂O, inspiratory time 0.35. In pressure-controlled mode, PIP was set in order to obtain the target expiratory flow with the same RR and PEEP. Inspiratory time was

adapted to achieve a zero end-inflatory flow on the flow-pressure loop in order to evaluate compliance accurately. Three sets of loops were recorded for every setting. Pressure and volume calibration were repeated every time a setting was modified.

As the system did not allow replaying the loops obtained by ventilating the lung model, the three observers analysed successive loops obtained with identical lung model and ventilator settings. In order to quantify the similarity of the successive loops that the observers analysed, the similarity of primary parameters (PIP, PEEP, RR and expiratory \dot{V}_T) calculated by the monitor was evaluated on a sample of 18 loops by the intraclass correlation [R] [5, 6].

$$R = \frac{\text{MSL} - \text{MSR}}{\text{MSL} + \text{MSR}}$$

where MSL was mean squares between results of loops generated with same ventilator and lung model setting and MSR residual mean square. The 95% confidence intervals were obtained as follows [5]:

$$95\% \text{ CI of } \bar{z} = z \pm 1.96\sigma_z$$

where $\bar{z} = 0.5 \log \frac{1+R}{1-R}$, $\sigma_z^2 = \frac{1}{K-1.5}$, K the number of pairs of measurements. A conversion table gave R values corresponding to the CI. A very good agreement (i.e. $R \geq 0.91$ [5]) was required for further analysis.

Statistical analysis

Means of Rrs, infl. and Crs, infl. calculated by the observers were compared by two analysis of variance (ANOVA) with mixed effects, corresponding to a nested model [7]. In both ANOVA the main factor was the observer factor. The factor nested in the main factor was the parameter on which the observer effect was evaluated. For the analysis of the effect of the observer on compliance measurement, flow was nested in the mode of ventilation, which was nested in resistance, which was nested in compliance, which was nested in observer. For the analysis of the effect of the observer on resistance measurement, the nesting hierarchy was identical except that compliance was nested in resistance, which was nested in observer. Each observer performed 72 measurements of Crs, infl. and 72 measurements of Rrs, infl. , 36 in volume-controlled and 36 in pressure-controlled mode. The residual was estimated from three repeated measurements.

The difference in mean values of Rrs, infl. and Crs, infl. calculated by two observers we wanted to detect was set at 10%. To guarantee an α value of 0.05 and a β value of 0.20, three observers (O) were needed. If mean Rrs, infl. and mean Crs, infl. calculated by the three observers were not significantly different, interobserver agreement for Rrs, infl. and Crs, infl. was estimated by R [6]:

$$R = \frac{\text{MSL} - \text{MSR}}{\text{MSL} + (m-1)\text{MSR}}$$

where m was the number of observers. Considering the R values, the interobserver agreement was considered very good (≥ 0.91), good (0.90–0.71), moderate (0.70–0.51), poor (0.50–0.31) or very bad (≤ 0.31) [5].

Table 1 Compliance *Crs,infl.* and resistance *Rrs,infl.* measured by the monitor during inflation by the ventilator. Values are mean (SD)

Ventilation mode	<i>Crs,infl.</i> ^a				<i>Rrs,infl.</i> ^b	
	C10	C15	C20	C30	R20	R50
Volume controlled	9.27 (0.19)	13.00 (0.54)	18.56 (0.55)	28.62 (2.38)	23.00 (1.51)	50.25 (2.38)
Pressure controlled	9.42 (0.19)	13.87 (0.52)	20.43 (1.14)	32.53 (1.33)	23.25 (1.58)	48.88 (4.9)

^a C10, C15, C20, C30: compliance in ml/cmH₂O set on lung model ($n = 4$ measurements for every setting); ^b R20, R50: resistance in cmH₂O/l per s set on the model ($n = 8$ measurements by setting)

Table 2 Differences in compliance *Crs,infl.* and resistance *Rrs,infl.* measurements between pairs of observers

	n^a	Mean difference (SD)		
		O ₁ -O ₂	O ₁ -O ₃	O ₂ -O ₃
Δ Crs, infl. (ml/cmH ₂ O)	72	+0.08 (0.38)	-0.001 (0.37)	-0.09 (0.35)
Δ Rrs, infl. (cm H ₂ O/l per s)	72	-0.01 (2.12)	-0.222 (1.89)	-0.21 (1.81)

^a Paired loops analysed by two observers (O) for every difference (Δ)

Results

Accuracy of the volume and pressure measuring devices

The accuracy of the volume measurements ranging from 20 to 400 ml, corresponding to flows from 0.6 to 12 l/min (linear range), was $\leq 5.8\%$ of the true volume using No.0 pneumotachograph. The accuracy of the volume measurements ranging from 20 to 200 ml, corresponding to flows from 0.6 to 6 l/min (suggested range of use), was quite good, being $\leq 1.3\%$ of the true volume. The accuracy of the volume measurements ranging from 50 to 1000 ml, corresponding to flows from 1.5 to 30 l/min (suggested range), was $\leq 5.3\%$ of the true volume using a No.1 pneumotachograph. With an endotracheal tube, the accuracy of the volume measurements ranging from 20 to 400 ml was $\leq 3.5\%$ using a No.0 pneumotachograph and the accuracy of the volume measurements ranging from 50 to 1000 ml was $\leq 5\%$ using a No.1 pneumotachograph. The accuracy of the pressure measurements ranging from 2 to 70 cmH₂O was $\leq 2.5\%$ of the true values. The CV of the volume measurements was $\leq 1.1\%$ with a No.0 pneumotachograph, $\leq 1.3\%$ with a No.1 pneumotachograph and with an endotracheal tube, CV were $\leq 1\%$ with a No.0 pneumotachograph and $\leq 1.9\%$ with a No.1 pneumotachograph. The CV of the pressure measurements was $\leq 1.7\%$.

Accuracy of *Rrs,infl.* and *Crs,infl.* measurements

Mean (SD) values of *Crs,infl.* and *Rrs,infl.* measured by the monitor at each setting of the lung model during inflation by the ventilator are given in Table 1. These correspond to *Crs,infl.* values from 83 to 107% of set values in the volume-controlled mode and values from 88 to 114% of set values in the pressure-controlled mode.

The CVs of *Crs,infl.* measurements were $< 8\%$. *Rrs,infl.* values were 90 to 125% of set values in the volume-controlled mode and 84 to 125% in the pressure-controlled mode, and the CVs of *Rrs,infl.* measurements were $< 10\%$.

Assessment of interobserver agreement for *Rrs,infl.* and *Crs,infl.* determination

Effect of main factor: No significant observer's effect on *Crs,infl.* measurement was found. The interobserver agreement was very good since $R = 0.987$ and CI = 0.979 to 0.992. No significant observer's effect on *Rrs,infl.* measurement was found. And the interobserver agreement was also very good: $R = 0.991$ and CI = 0.985 to 0.994. The mean difference in the *Crs,infl.* and *Rrs,infl.* determinations was therefore less than 10%. Indeed, mean differences in *Crs,infl.* and *Rrs,infl.* measurements between pairs of observers (i.e. O₁-O₂, O₂-O₃, O₁-O₃) were $< 1\%$ (Table 2).

Effect of nested factors: Using this experimental design to compare mean values of *Crs,infl.* obtained by three observers, most of the variability (99%) was found in the compliance effect, as expected, since it corresponded to the two compliance levels set on the lung model. The resistance effect was not significant, but the effect of the mode of ventilation was significant ($p < 0.001$) corresponding to slightly increased compliance values in the pressure-controlled mode. The effect of flow setting was also significant ($p < 0.001$), but no general rule could be attributed.

Similarly, comparing the mean values for *Rrs,infl.* obtained by three observers, most of the variability (99.7%) was found in the resistance effect, as expected, since it also corresponded to the two resistance levels set on the lung model. The effect of compliance was

not significant. On the contrary the effect of the ventilation mode was significant ($p < 0.01$), corresponding most often to a slightly lower $R_{rs, infl.}$ in the pressure-controlled mode, but this trend was not systematically found on all blocks of nine values of $R_{rs, infl.}$ calculated for each ventilation mode following the nested model, which included three repeated values for each of the three tested flows. The effect of flow was not significant.

Residuals represented only a small proportion of the total variance of $C_{rs, infl.}$ and $R_{rs, infl.}$ determination. The very good reproducibility of primary parameters of successive loops contributed to this small residual: indeed, RR was 21/min on all loops, and R was > 0.95 for PIP, PEEP, and V_T .

Discussion

The determination of respiratory mechanics by this monitoring system requires only a short interruption of the ventilation to insert the pneumotachograph. It should be noted that, due to the dead space in the pneumotachographs tested, the system that we have assessed is suitable for use in paediatric rather than neonatal intensive care. However, volume and pressure channels can be calibrated with any pneumotachograph and, in particular, with a pneumotachograph with a smaller dead space if it has to be used in neonatal intensive care. Moreover, as the Fleisch pneumotachograph is very sensitive to errors due to condensation if not heated, especially in the ventilator circuit, a heated pneumotachograph should be used for all in vivo measurements to avoid errors due to condensation. The child's respiratory efforts can be detected on pressure-time curves, on flow-time trace and on volume-pressure loops. Finally successive loops are superimposed and allow the evaluation of the reproducibility of successive loops. The resistance and compliance determination itself does not require any manoeuvre, disconnection or occlusion. The intervention of the observer is limited to the determination of two (in pressure-controlled mode) or three slopes (in volume-controlled mode). This can be achieved by any member of the medical team, as shown by this study.

Few studies have assessed the accuracy of volume and pressure measurement provided by a commercially available respiratory monitoring system. Our study defined the working range of our flow and pressure measuring apparatus. The range over which 5% accuracy was achieved by our monitor was 0.6 to 9 l/min when connected to No.0 pneumotachograph and 1.5 to 30 l/min when connected to No.1 pneumotachograph, even with an endotracheal tube. These results must be compared with the results of the very sophisticated assessment of the Bicare CP100 monitoring system, in which an identical level of accuracy was reached with an en-

dotracheal tube from -12 to $+18$ l/min [8]. Considering the pressure measuring device of our monitor, an accuracy of 2.5% was achieved from 2 to 70 cmH₂O, and in the latter study a 5% level of accuracy was achieved from -25 to 50 cmH₂O.

The accuracy of R_{rs} and C_{rs} measurements by monitoring systems has also been described in few studies. The accuracy within 17% of set values for $C_{rs, infl.}$ and within 25% for $R_{rs, infl.}$ was also quite good. Indeed, a similar level of accuracy (i.e. 20% of set values) was reached for measurement of respiratory mechanics compared to the known values of a neonatal lung simulator [8]. On the contrary, lower accuracy in a monitoring or diagnostic system (Bicare, SensorMedics 2600, Babylog) in measuring resistance and compliance of a lung model by the occlusion technique has been reported by others [9] since the mean error of compliance measurement ranged from -22 to 7% and of resistance from -3 to 189%. The source of measuring errors of $C_{rs, infl.}$ in vivo include high frequency and short inspiratory time leading recruitment of low time-constant alveolar units. In this study a mono-compartmental model was used and frequency was low, therefore this source of error seems unlikely. Moreover, we checked in pressure-controlled mode that flow reached zero at end-inflation. Increased viscosity due to a high FIO₂ may lead to inaccurate R_{rs} measurement. This source of error may not have contributed to the measuring error of $R_{rs, infl.}$ in our study since both calibration and measurements were made with the same FIO₂. Leakage around the endotracheal tube occurs frequently in paediatric patients and results in an underestimation of total applied pressure and flow. However, technical problems at connections were easily detected and corrected on our in vitro model. Therefore, it seems very unlikely that they could have contributed to the error of measurement of resistance and compliance.

The last objective of the study was to evaluate the error that the user could introduce in the measurement. No other study has evaluated the agreement between observers in determining respiratory parameters using a monitoring system. Our study did not demonstrate any significant difference between mean values of parameters determined by three observers. Moreover, excellent agreement between the values they calculated on paired loops was obtained even though the observers had different levels of training. Indeed, two of them had never used the monitor before. Mean differences in $C_{rs, infl.}$ and $R_{rs, infl.}$ determinations were smaller than 1% and thus clinically irrelevant. The effect of the ventilation mode was significant, though it represented a negligible part of the overall variance. Indeed, we almost invariably observed that $C_{rs, infl.}$ was slightly increased in pressure-controlled as compared to volume-controlled mode. Calibration differences could hardly have explained a systematic increase of $C_{rs, infl.}$ in pres-

sure-controlled mode. To obtain a higher value of Crs,infl. in pressure-controlled mode, either $V_T + V_{\text{trap}}$ was overestimated or PIP –PEEPv was underestimated. As the latter was automatically determined by the monitor, it can be suggested that the observers may have determined slopes leading to increased Vtrap and increased Crs,infl. determination. This difference did not reach 10% of the known value, but this small difference must be taken into account when investigating longitudinally the same subject ventilated with different ventilation modes. We observed, though less consistently, that Rrs,infl. values were slightly lower in pressure-controlled mode. We also observed a significant flow effect for Crs,infl. determination. However, as no general rule could be attributed for this last effect, it can be suggested that the level where we introduced this factor in the hierarchy of our nested model might have contributed to this significance. Finally, our study has the advantage of having determined the measurement variability due to data acquisition and ventilation settings, whereas this information is usually included in the intrasubject variability. The short-term intrasubject CV of Crs and Rrs measured with different techniques in ventilated children varies from 3 to 25% [10–12]. It was important to define the procedural variability of our monitor and to show that this variability remained small when com-

pared to intrasubject variability. And this was the case since the CV of Crs,infl. measurements was < 8% and the CV of Rrs,infl. measurement was < 10%.

In conclusion, this study demonstrates that this commercially available bedside monitoring system, which is able to give qualitative and quantitative information for diagnosis of obstructive or restrictive disease, detection of secretions before clinical signs [13] and evaluation of intrinsic PEEP and amount of trapped gas [14], is also able to determine respiratory system compliance and resistance during inflation by the ventilator with sufficient accuracy for monitoring purposes. Moreover, the use of this monitoring system by either experienced or inexperienced users can be recommended since results obtained by different observers, even untrained ones, are similar. After this in vitro evaluation, further evaluation of this monitoring device will have to confirm in vivo the interobserver agreement for compliance and resistance determination, especially in the patient with respiratory disease. In fact, non-linearity of the expiratory slope of the flow-volume loops or secretions may increase the interobserver difference in parameter determination. Further assessment should also determine intrasubject variability of repeated measurements in order to determine the significance of individual parameter modification induced by treatment.

References

1. Riou Y, Storme L, Leclerc F (1992) Characterization of respiratory mechanics in ventilated neonates by inflation and interrupter methods. Proceedings of the 14th annual international conference of the IEEE Engineering in Medicine and Biology Society 14: 2413–2414
2. Logier R, ARCAS Group, Gehin AL, Bayart M, Couvrenz M, Staroswiecki M (1993) A new tool for respiratory monitoring and pulmonary mechanic measurements in mechanically ventilated children. Proceedings of the 15th annual international conference of the IEEE Engineering in Medicine and Biology Society 15: 1004–1005
3. Storme L, Riou Y, Leclerc F, Kacet N, Dubos JP, Gremillet C, Rousseau S, Lequien P (1992) Respiratory mechanics in mechanically ventilated new-borns: a comparison between passive inflation and occlusion methods. *Pediatr Pulmonol* 12: 203–212
4. Storme L, Riou Y, Logier R, Dubos JP, Kacet N, Rousseau S, Lequien P (1994) A new application of an old method for respiratory mechanics measurements: the passive inflation method in newborn infants during pressure-controlled ventilation. *Pediatr Pulmonol* 18: 244–254
5. Fermanian J (1984) Mesure de l'accord entre deux juges: cas quantitatif. *Rev Epidemiol Sante Publique* 32: 408–413
6. Armitage P, Berry G (1994) Intraclass correlation. In: Armitage P, Berry G (eds) *Statistical methods in medical research*. Blackwell, Oxford, pp 273–276
7. Lellouch J, Lazar P (1974) Une classification des schémas expérimentaux. In: Lellouch J, Lazar P (eds) *Methodes statistiques en expérimentation biologique*. Médecine-Science Flammarion, Paris, pp 207–219
8. Jackson EA, Coates AL, Gappa M, Stocks J (1995) In vitro assessment of infant pulmonary function equipment. *Pediatr Pulmonol* 19: 205–213
9. Hauschild M, Schmalisch G, Wauer RR (1994) Accuracy and reliability of commercial lung function diagnostic systems and respiratory monitors in newborn infants. *Klin Padiatr* 206: 167–174
10. Deanjean A, Guimaraes H, Migdal M, Miramand JL, Dehan M, Gaultier C (1992) Dose-related bronchodilator response to aerosolized salbutamol (albuterol) in ventilator-dependent premature infants. *J Pediatr* 120: 974–979
11. Brundage KL, Mohsini KG, Froese AB, Fisher JT (1990) Bronchodilator response to ipratropium bromide in infants with bronchopulmonary dysplasia. *Am Rev Respir Dis* 142: 1137–1142
12. Seear M, Wensley D, Werner H (1991) Comparison of three methods for measuring respiratory mechanics in ventilated children. *Pediatr Pulmonol* 10: 291–295
13. Leclerc F, Riou Y, Martinot A, Deschil-dre A, Nève V, Hue V, Fourier C (1996) Use of the flow-volume loop to detect secretions in ventilated children. *Intensive Care Med* 22: 88
14. Storme L, Riou Y, Leclerc F, Kacet N, Dubos JP, Gremillet C, Lequien P (1994) A simple method for determination of auto-PEEP in mechanically ventilated new-borns. In: Grauel EL, Wauer RR (eds) *Research in perinatal medicine* 3, Mosby, Berlin, pp 112–116