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**Measuring tidal breathing parameters using a volumetric vest in neonates with and without lung disease**

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Keywords:	infant, respiratory function, tidal breathing, chest wall



Review

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4 Measuring tidal breathing parameters using a volumetric vest in  
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7 neonates with and without lung disease  
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Running head: Measuring tidal breathing with a volumetric vest

## Summary

Lung function measurement is difficult in unsedated infants; tidal breathing parameters are a useful non-invasive surrogate, but even these measurements cause disturbance from applying a facemask. We investigated a novel volumetric vest system (FloRight), which measures volume changes of the respiratory system from changes in the magnetic fields induced by current-carrying coils around the entire chest and abdomen.

Using a facemask and ultrasonic flowmeter as comparator, we assessed the validity and repeatability of tidal breathing parameters measured by FloRight in 10 healthy newborn infants during natural sleep. We also assessed the effect of a facemask on tidal volume and tidal expiratory flow parameters. To assess the ability of the FloRight system to detect disease, we compared the healthy infants with 11 infants suffering from bronchopulmonary dysplasia.

Tidal parameters with the FloRight vest corresponded closely with facemask measurements. Mean difference, mask minus vest, for tidal volume was 0.096mL ( $p < 0.05$ ), with limits of agreement +4.5 to -4.3mL. Coefficient of repeatability was similar for mask and vest measurements. Tidal volume measured by FloRight with mask in place (20.6mL) was significantly higher than without mask (16.1mL), but tidal expiratory flow parameters were not altered. FloRight measurements of tidal parameters were markedly different between the two groups of infants, with tidal volume per Kg significantly higher and tidal expiratory flow parameters significantly lower.

Our findings suggest that the FloRight system is able to measure tidal breathing parameters accurately, in healthy newborn infants, without prior calibration on the infant. It appears to have at least sufficient sensitivity to detect severe respiratory disease.

Keywords: Infant, respiratory function, tidal breathing, chest wall.

## Introduction

Assessing lung function in infants is difficult and time-consuming, and in certain situations virtually impossible with current techniques. Methods such as rapid thoracic compression and its raised volume refinement have advanced our understanding of infant lung disease<sup>1</sup>.

Because of the need for sedation, however, they are only practicable in stable infants without severe or acute lung disease. The need for sedation and the time taken for measurements also limits their clinical applicability. Measurement of tidal breathing parameters<sup>2-4</sup> is an attractive alternative, giving an indirect but non-invasive indication of lung function. They can be measured and repeated rapidly, and sedation is not always needed. However, the application of a facemask to capture respiratory airflow is problematic: it often causes disturbance or arousal, and there are suggestions<sup>3;5;6</sup> that both the trigeminal stimulation and the deadspace of a mask may alter the pattern of tidal breathing.

To avoid these problems, attempts have been made to measure tidal breathing parameters at the chest wall using respiratory inductive plethysmography (RIP)<sup>7</sup>. However, this requires prior calibration with airflow measured at a facemask if absolute volumes are to be measured<sup>8</sup>, which negates most of the advantage of the technique. Using uncalibrated RIP has been advocated<sup>9</sup>, but the accuracy of tidal parameters measured in this way has been questioned<sup>10</sup>. Even when RIP is calibrated before use, changes in band position or in the pattern of breathing can invalidate the calibration. A method of measuring respiratory airflow accurately at the chest wall without mask calibration would be highly desirable.

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3 The FloRight system (Volusense, Kongsvinger, Oslo, Norway) consists of two continuous wire  
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5 coils sewn into a vest worn over the entire chest and abdomen, the upper coil covering the  
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7 chest, the lower the abdomen. A weak (100mA) alternating current is passed through the  
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9 coils, resulting in a magnetic field around the child's torso which is detected by an external  
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11 magnetic field sensor. With breathing movements, the volume contained within the coils  
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13 expands and contracts, causing proportional changes in the magnetic field that is generated.  
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18 The device can therefore directly measure changes in the volume of the respiratory system,  
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20 and these volume changes can be differentiated digitally to yield a flow signal – and hence  
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22 measure tidal breathing parameters.  
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27 Basic laboratory studies (Unpublished observations, Volusense) have suggested that the  
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29 measurement of volume change is accurate and requires only electrical calibration with a  
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31 cylindrical volume reference coil. The primary aim of this study was to validate the  
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33 measurement system in healthy newborn infants – ie to demonstrate that it gives accurate  
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35 measurements of tidal breathing parameters without needing calibration on the infant  
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37 against airflow measured from a mask at the airway opening. Our primary hypothesis is that  
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39 in spontaneously breathing healthy term newborns, the FloRight vest gives estimates of  
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41 tidal volume which are similar to estimates measured from flow at the airway opening.  
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46 Secondary aims were to quantify and compare the repeatability of tidal breathing  
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48 measurements using the two methods – chest wall (vest) and airway opening (mask)  
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50 measurements - and to compare tidal breathing parameters (measured at the chest wall)  
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52 with and without a mask in place. A further aim was to assess whether it was possible, using  
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54 tidal parameters measured with the system, to distinguish between healthy newborn  
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56 infants and infants with bronchopulmonary dysplasia (BPD).  
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## Patients and Methods

The study protocol was approved by the East Sussex Research Ethics Committee and all parents gave written informed consent. In the first part of the study (validation), healthy newborn infants were studied simultaneously using the FloRight system and a system measuring airflow via a mask using an ultrasonic flowmeter (Exhalyzer D, EcoMedics AG, Duernten, Switzerland). Ten infants under a week of age and over 37 weeks gestation, without a history of respiratory symptoms or congenital abnormalities were studied on the postnatal ward of the Royal Sussex County Hospital, Brighton, UK.

Firstly, a FloRight vest of suitable size – fitting snugly but without constriction – was put on over a single thin layer of clothing. The correct size of vest was gauged by measuring the chest circumference at nipple level, and the vest was placed covering the infant from armpit to groin. In this position the junction between the upper and lower coils of the vest is approximately at the lower border of the ribcage. The FloRight system was calibrated with the magnetic field detector in place and the volume reference cylinder at the side of the infant. For measurement the magnetic field detector was positioned so that the vest was aligned with the two fins and equidistant between them, with the baby lying on a surface 40 cm below the fins. The EcoMedics system was calibrated with a 100 ml Hans Rudolph volumetric syringe (Hans Rudolph Inc, Shawnee, Kansas, US). Once the baby was in quiet natural sleep, a firm face mask with inflatable cushion rim was placed over the baby's nose and mouth, then collection of two minutes of tidal breathing data was commenced

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3 simultaneously with the two systems. These recordings will be designated V1 (FloRight vest)  
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5 and M1 (EcoMedics mask). The mask was then removed, and a two minute epoch of tidal  
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7 breathing was recorded using FloRight alone, with no mask in place – designated V1A .  
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10 Finally, a further two-minute epoch was recorded using both systems for repeatability  
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12 measurements – designated V2 and M2. Figure 1 shows the mask and vest in place  
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14 simultaneously during data collection. The data sampling frequency was 200 Hz for the  
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For calculation of the tidal breathing parameters, the traces were first inspected visually to select a 10-breath segment of stable tidal breathing with the following characteristics: no obvious artefacts, no sighs, no obvious changes in depth of breathing or baseline.

Simultaneous 10-breath segments from M1/V1, M2/V2, and from V1A were then analysed in detail to calculate the following parameters, measured breath-by-breath then averaged over the 10-breath segment:

1. Tidal volume ( $V_T$ ) in ml, and per Kg body weight ( $V_T/Kg$ )
2. Time to peak tidal expiratory flow as a ratio of expiratory time ( $T_{PTEF}/T_E$ )

For the vest recordings only, the following additional tidal parameters were calculated from the traces:

3. Ratio of expiratory time to inspiratory time ( $T_E/T_I$ )
4. Expiratory flow at 50% of tidal volume as a ratio of peak tidal expiratory flow  
 $(TEF_{50}/PTEF)^2$
5. Expiratory flow at 25% of tidal volume as a ratio of peak tidal expiratory flow  
 $(TEF_{25}/PTEF)^2$



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6. Centre of gravity along the volume axis for the tidal expiratory flow-volume curve (FVg). This is the dimensionless value along the volume axis (taking 0 as the start of expiration and 1 as the end of expiration) such that the areas under the curves to right and left of this point are equal. A symmetrical curve with peak flow occurring at mid-tidal volume would have  $FVg=0.5$ ; any shift of peak tidal expiratory flow towards the start of inspiration will give values below 0.5.

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The parameters were compared, using paired t-test and Bland-Altman analysis, between pairs of recordings as follows.

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M1 and V1 were compared to assess the validity of the FloRight vest measurements.

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M1 was compared with M2, and V1 with V2, to assess repeatability of both the mask and vest measurements.

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V1 was compared with V1A to assess the effect of a facemask on tidal breathing parameters.

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For the second part of the study, 11 oxygen-dependent infants with bronchopulmonary dysplasia (BPD, defined as persistent supplemental oxygen need beyond 36 weeks gestation, following neonatal respiratory failure) were measured, using the same protocol as above as far as possible. Mask measurements were not possible because of the nasal cannula oxygen (the oxygen flow caused a large baseline drift), so only V1 and V2 were recorded. The coefficient of repeatability of the vest measurements of tidal breathing parameters was calculated. In addition, the tidal measurements were compared with the 10 healthy term infants using two-sample t-tests.

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3 The characteristics of the infants studied are summarised in Table 1. Although the weight  
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5 and length of the two groups is similar, the BPD infants, as would be expected, were short  
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7 and light for age even when corrected for prematurity.  
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## 10 11 Results

### 12 13 Validity

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19 Figure 2 shows Bland-Altman plots of M1 vs V1 for  $V_T$  and for  $T_{PTEF}/T_E$ , with mean difference  
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21 and limits of agreement shown. There was no significant difference in either parameter, and  
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23 there was close correspondence between the paired measurements as shown by the small  
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25 mean differences (Mask minus Vest  $V_T +0.096$  ml,  $T_{PTEF}/T_E -0.01$ ) and narrow limits of  
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27 agreement ( $V_T +4.5$  ml to  $-4.3$  ml,  $T_{PTEF}/T_E +0.32$  to  $-0.35$ ).  
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### 31 32 Repeatability

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35 Repeatability was expressed as the coefficient of repeatability (CR), defined as twice the  
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37 standard deviation of the differences between measurements<sup>11</sup>. We have also expressed it  
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39 as a percentage of the mean value (CR%). Table 2 shows CR and CR% for: M1 vs M2 in  
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41 healthy infants, V1 vs V2 in healthy infants, and V1 vs V2 in BPD infants.  
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### 46 47 Effect of facemask

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50 Table 3 shows mean difference, 95% confidence intervals of mean difference, and limits of  
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52 agreement for the tidal parameters, comparing V1 with V1A in the healthy infants. Tidal  
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54 volume is significantly higher with the mask in place, as would be expected because of the  
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56 additional deadspace. However, there was no significant difference in any of the tidal  
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58 expiratory flow parameters.  
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3 Changes with disease  
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7 Figure 3 shows typical flow-time and flow-volume traces recorded by the FloRight device in  
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9 a healthy infant and a BPD infant: a clear difference can be seen in the pattern of expiratory  
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11 flow (“sinusoidal” versus “quadrilateral” as originally described by Morris and Lane<sup>12</sup>). Table  
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13 4 shows mean difference and 95% confidence intervals of mean difference, comparing V<sub>T</sub> in  
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15 healthy infants with V<sub>T</sub> in BPD infants. There were significant differences in tidal volume  
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17 (corrected for body weight) and all tidal expiratory flow parameters. V<sub>T</sub> per Kg was  
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19 significantly higher in BPD infants (as expected due to increased physiological deadspace),  
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21 while all the tidal expiratory flow parameters were significantly lower. Ratio of inspiratory to  
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23 expiratory time (T<sub>I</sub> / T<sub>E</sub>) showed only a non-significant trend to be lower.  
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## 34 Discussion

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38 We have demonstrated that a novel volumetric vest system is able to measure both tidal  
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40 volume and tidal expiratory flow parameters in unsedated infants, without prior calibration  
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42 on the infant, and to yield values in healthy infants which are very close to those measured  
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44 directly from airflow at the airway opening. The measurements using the vest are as  
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46 repeatable as those measured at the airway opening. Furthermore, we have shown that  
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48 tidal measurements made using this system are able to differentiate infants with  
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50 bronchopulmonary dysplasia from healthy term infants.  
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56 Previous work using RIP has yielded conflicting results. Stick et al<sup>9</sup>, using uncalibrated RIP,  
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58 showed close agreement between T<sub>PTEF</sub>/T<sub>E</sub> values from RIP with those from mask and  
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60 pneumotachograph in unsedated healthy newborn infants. However, Jackson et al<sup>10</sup>, using

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3 a different uncalibrated RIP system in unsedated newborns and sedated older infants were  
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5 unable to replicate this. In their study, RIP-measured  $T_{PTEF}/T_E$  was consistently lower, with  
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7 wide limits of agreement. Neither study was designed to measure tidal volume.  
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11 Our values for tidal parameters in the healthy infants, measured both by mask and by vest,  
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13 are very similar to published values in healthy term neonates measured by mask<sup>13-15</sup>. This,  
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15 as well as our finding that tidal expiratory flow parameters (unlike tidal volume) were not  
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17 altered by the presence of a mask, suggests that existing normative values are appropriate  
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19 in interpreting measurements made using this vest system. Our figures for repeatability of  
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21  $T_{PTEF}/T_E$ , both with mask (CR 41%) and vest (CR 37%), are also similar to published values<sup>13</sup>,  
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23 and demonstrate how variable this parameter is in newborn infants. This is a significant  
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25 limitation of  $T_{PTEF}/T_E$ , however measured, and suggests that the parameters with better  
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27 repeatability such as FVg may be worth exploring .  
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35 Clearly caution is needed in applying our conclusions on the validity of the system. We were  
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37 not able to make mask measurements in our BPD infants because of the administration of  
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39 nasal cannula oxygen, and therefore were not able to show whether the Floright system  
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41 makes valid measurements in the presence of chest distortion. All our measurements were  
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43 made during spontaneous tidal breathing in infants lying supine, so that we cannot  
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45 comment on the validity of measurements in prone or side-lying infants, in older children  
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47 measured in a sitting position, or in artificially ventilated infants. All our healthy neonates  
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49 were above 2Kg weight: it is not yet clear whether the system will be accurate in small  
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51 preterm infants.  
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58 At the beginning of the study we encountered difficulty in calibrating the equipment in an  
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60 electrically “noisy” environment (eg near television screens): a software change was

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3 required to resolve this problem. Interference from nearby devices producing a high  
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5 frequency changing magnetic field may still cause problems, in some settings, but would be  
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7 likely to produce a “noisy” trace, rather than inaccurate measurements. The equipment is  
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9 currently large and cumbersome, making its use in acute or intensive care settings difficult:  
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11 we understand that design changes to modify this problem are planned.  
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17 Despite these caveats, our findings suggest that this is an accurate technique for measuring  
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19 tidal breathing without the need for a face mask. This technique has the potential to  
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21 measure tidal flow parameters in situations where a mask is not tolerated (eg tachypnoea,  
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23 awake infants) or mask measurements are problematic (eg oxygen therapy, continuous  
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25 positive airway pressure, non-invasive ventilation). The volume changes can also be  
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27 partitioned into chest and abdominal components, giving the potential to measure  
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29 thoracoabdominal asynchrony in the context of acute respiratory disease or sleep-  
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31 disordered breathing. Further work is needed to validate the technique in these settings.  
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	Healthy	Bronchopulmonary Dysplasia
Number of infants	10	11
Weight (Kg)	3.7 (0.4)	4.0 (1.6)
Weight Z (SD) score	+0.13 (0.83)	-2.59 (1.11)
Length (cm)	52 (2.39)	52 (7.6)
Length SD Z (SD) score	+0.09 (0.82)	-2.17 (1.38)
Birth Gestation (weeks)	40 (1.3)	29 (4.6)
Age at test (days)	1.4 (0.5)	146 (71)

Table 1: Characteristics of infants studied, showing mean (SD). Z scores for weight and length are calculated as the number of SD above or below the predicted mean from growth charts; for the BPD infants, age is corrected for prematurity.

For Peer Review

	Healthy infants - Mask		Healthy infants - Vest		BPD infants - Vest	
	Mean value (SD)	CR (CR%)	Mean value (SD)	CR (CR%)	Mean value (SD)	CR (CR%)
$V_T$ (ml)	20.66 (5.35)	7.2 (37%)	20.56 (4.10)	8.4 (41%)	26.84 (5.05)	6.6 (23%)
$V_T$ (ml/Kg)	5.43 (1.53)	2.0 (37%)	5.40 (1.23)	2.2 (41%)	7.01 (1.32)	1.83 (23%)
$T_{PTEF}/T_E$	0.50 (0.09)	0.20 (41%)	0.51 (0.14)	0.18 (37%)	0.217 (0.094)	0.14 (65%)
$T_E / T_I$	1.07 (0.21)	0.43 (38%)	1.04 (0.18)	0.47 (45%)	1.30 (0.42)	0.89 (67%)
$TEF_{50}/PTEF$			0.920 (0.068)	13.3 (14%)	0.744 (0.125)	16.1 (22%)
$TEF_{25}/PTEF$			0.787 (0.116)	23.1 (30%)	0.457 (0.148)	15.5 (34%)
FVg			0.501 (0.028)	0.02 (8%)	0.430 (0.037)	0.04 (10%)

Table 2. Tidal breathing parameters, showing mean values, repeatability coefficient (CR) and CR as percent of mean value (CR%), for mask and vest measurements in healthy infants, and for mask measurements in BPD infants.



	With Mask Mean (SD)	Without Mask Mean (SD)	Mean Difference (95%Confidence Interval)
Tidal Volume (ml)	20.56 (4.10)	16.096 (3.79)	4.67 * (+1.64 to +7.29)
$T_{PTEF}/T_E$	0.51 (0.14)	0.53 (0.15)	0.01 (-0.09 to +0.06)
$TEF_{50}/PTEF$	0.918 (0.043)	0.849 (0.095)	0.069 (-0.010 to +0.148)
$TEF_{25}/PTEF$	0.776 (0.102)	0.772 (0.137)	0.004 (-0.038 to +0.047)
FVg	0.498 (0.020)	0.502 (0.028)	-0.005 (-0.02 to +0.01)

Table 3. Tidal breathing parameters in healthy newborn infants measured by volumetric vest, comparing values with and without face mask in place. \* =  $p < 0.05$

	Normal (n=10)	BPD (n=11)	p value
$V_T / Kg$ (ml/Kg)	5.40 (1.23)	7.01 (1.32)	0.009
$T_{PTEF}/T_E$	0.506 (0.150)	0.217 (0.094)	0.00004
$T_E / T_I$	1.04 (0.18)	1.30 (0.42)	0.08
$TEF_{50}/PTEF$	0.920 (0.068)	0.744 (0.125)	0.009
$TEF_{25}/PTEF$	0.787 (0.116)	0.457 (0.148)	0.00002
FVg	0.501 (0.028)	0.430 (0.037)	0.00009

Table 4. Tidal breathing parameters measured by volumetric vest in healthy and BPD infants, showing mean (SD) values and p value for comparison (two-sample t-test).

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Figure 1: Study setup, showing both FloRight vest and mask with ultrasonic flowmeter in place.  
194x153mm (96 x 96 DPI)

Review

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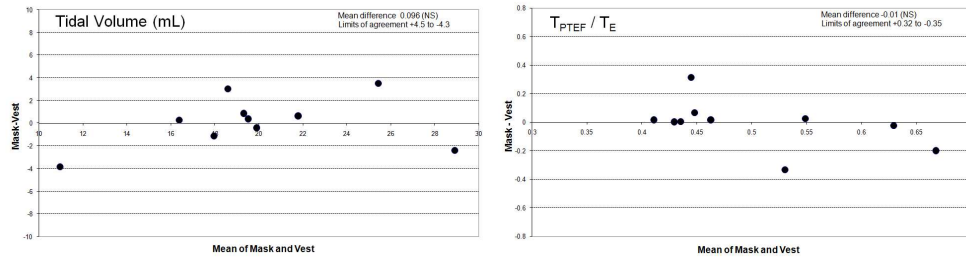


Figure 2: Bland-Altman plots comparing tidal parameters measured simultaneously with mask (ultrasonic flowmeter system) versus vest (FloRight system); tidal volume on left-hand plot, TPTEF/TE on right-hand plot. 533x144mm (96 x 96 DPI)

Peer Review

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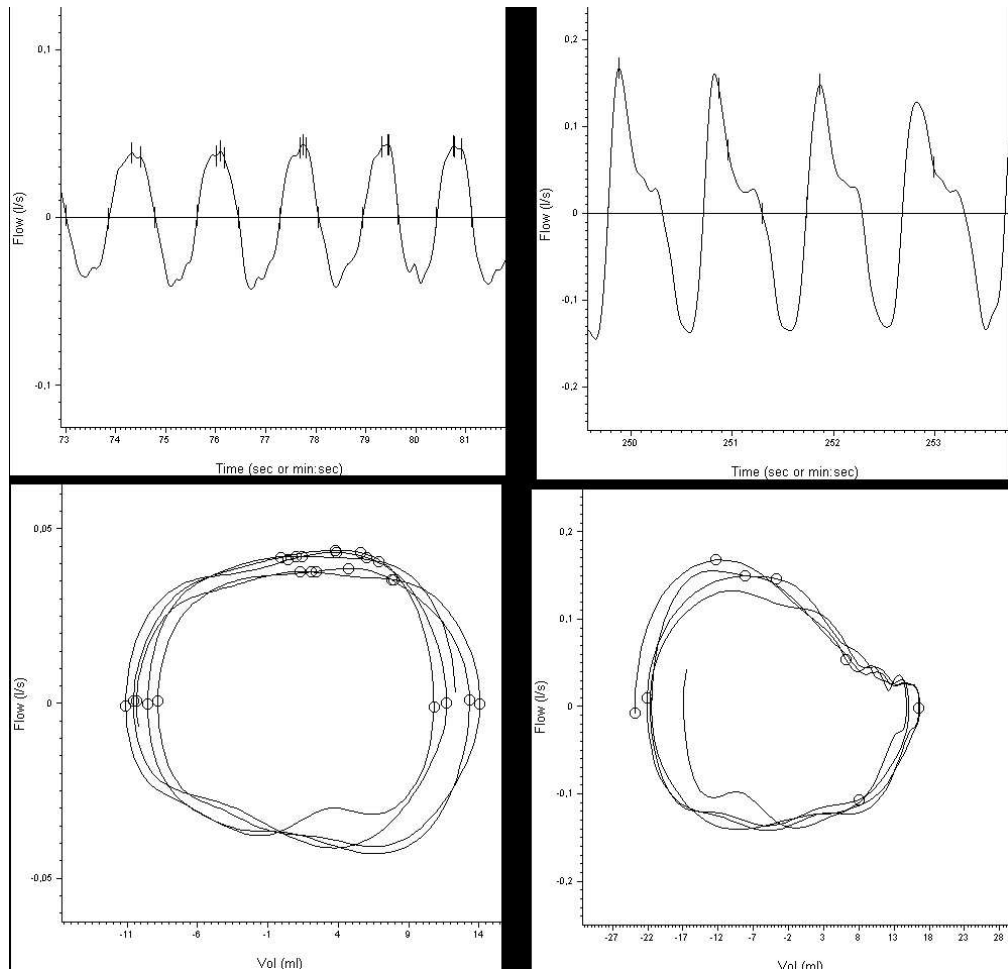


Figure 3: Sample flow-time (upper plots) and flow-volume (lower plots) for two infants: healthy newborn infant on the left, infant with bronchopulmonary dysplasia on the right. 262x252mm (96 x 96 DPI)

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4 Measuring tidal breathing parameters using a volumetric vest in  
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7 neonates with and without lung disease  
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11 Olden C RSCN, Symes E RSCN, Seddon P MB ChB.  
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24  
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29 Eriksen of Volusense, Norway.  
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Running head: Measuring tidal breathing with a volumetric vest

## Summary

Lung function measurement is difficult in unsedated infants; tidal breathing parameters are a useful non-invasive surrogate, but even these measurements cause disturbance from applying a facemask. We investigated a novel volumetric vest system (FloRight), which measures volume changes of the respiratory system from changes in the magnetic fields induced by current-carrying coils around the entire chest and abdomen.

Using a facemask and ultrasonic flowmeter as comparator, we assessed the validity and repeatability of tidal breathing parameters measured by FloRight in 10 healthy newborn infants during natural sleep. We also assessed the effect of a facemask on tidal volume and tidal expiratory flow parameters. To assess the ability of the FloRight system to detect disease, we compared the healthy infants with 11 infants suffering from bronchopulmonary dysplasia.

Tidal parameters with the FloRight vest corresponded closely with facemask measurements. Mean difference, mask minus vest, for tidal volume was 0.096mL ( $p < 0.05$ ), with limits of agreement +4.5 to -4.3mL. Coefficient of repeatability was similar for mask and vest measurements. Tidal volume measured by FloRight with mask in place (20.6mL) was significantly higher than without mask (16.1mL), but tidal expiratory flow parameters were not altered. FloRight measurements of tidal parameters were markedly different between the two groups of infants, with tidal volume per Kg significantly higher and tidal expiratory flow parameters significantly lower.

Our findings suggest that the FloRight system is able to measure tidal breathing parameters accurately, in healthy newborn infants, without prior calibration on the infant. It appears to have at least sufficient sensitivity to detect severe respiratory disease.

Keywords: Infant, respiratory function, tidal breathing, chest wall.

## Introduction

Assessing lung function in infants is difficult and time-consuming, and in certain situations virtually impossible with current techniques. Methods such as rapid thoracic compression and its raised volume refinement have advanced our understanding of infant lung disease<sup>1</sup>.

Because of the need for sedation, however, they are only practicable in stable infants without severe or acute lung disease. The need for sedation and the time taken for measurements also limits their clinical applicability. Measurement of tidal breathing parameters<sup>2-4</sup> is an attractive alternative, giving an indirect but non-invasive indication of lung function. They can be measured and repeated rapidly, and sedation is not always needed. However, the application of a facemask to capture respiratory airflow is problematic: it often causes disturbance or arousal, and there are suggestions<sup>3;5;6</sup> that both the trigeminal stimulation and the deadspace of a mask may alter the pattern of tidal breathing.

To avoid these problems, attempts have been made to measure tidal breathing parameters at the chest wall using respiratory inductive plethysmography (RIP)<sup>7</sup>. However, this requires prior calibration with airflow measured at a facemask if absolute volumes are to be measured<sup>8</sup>, which negates most of the advantage of the technique. Using uncalibrated RIP has been advocated<sup>9</sup>, but the accuracy of tidal parameters measured in this way has been questioned<sup>10</sup>. Even when RIP is calibrated before use, changes in band position or in the pattern of breathing can invalidate the calibration. A method of measuring respiratory airflow accurately at the chest wall without mask calibration would be highly desirable.



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3 The FloRight system (Volusense, Kongsvinger, Oslo, Norway) consists of two continuous wire  
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5 coils sewn into a vest worn over the entire chest and abdomen, the upper coil covering the  
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7 chest, the lower the abdomen. A weak (100mA) alternating current is passed through the  
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9 coils, resulting in a magnetic field around the child's torso which is detected by an external  
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11 magnetic field sensor. With breathing movements, the volume contained within the coils  
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13 expands and contracts, causing proportional changes in the magnetic field that is generated.  
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18 The device can therefore directly measure changes in the volume of the respiratory system,  
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20 and these volume changes can be differentiated digitally to yield a flow signal – and hence  
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22 measure tidal breathing parameters.  
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27 Basic laboratory studies (Unpublished observations, Volusense) have suggested that the  
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29 measurement of volume change is accurate and requires only electrical calibration with a  
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31 cylindrical volume reference coil. The primary aim of this study was to validate the  
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33 measurement system in healthy newborn infants – ie to demonstrate that it gives accurate  
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35 measurements of tidal breathing parameters without needing calibration on the infant  
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37 against airflow measured from a mask at the airway opening. Our primary hypothesis is that  
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39 in spontaneously breathing healthy term newborns, the FloRight vest gives estimates of  
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41 tidal volume which are similar to estimates measured from flow at the airway opening.  
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47 Secondary aims were to quantify and compare the repeatability of tidal breathing  
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49 measurements using the two methods – chest wall (vest) and airway opening (mask)  
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51 measurements - and to compare tidal breathing parameters (measured at the chest wall)  
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53 with and without a mask in place. A further aim was to assess whether it was possible, using  
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55 tidal parameters measured with the system, to distinguish between healthy newborn  
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57 infants and infants with bronchopulmonary dysplasia (BPD).  
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## Patients and Methods

The study protocol was approved by the East Sussex Research Ethics Committee and all parents gave written informed consent. In the first part of the study (validation), healthy newborn infants were studied simultaneously using the FloRight system and a system measuring airflow via a mask using an ultrasonic flowmeter (Exhalyzer D, EcoMedics AG, Duernten, Switzerland). Ten infants under a week of age and over 37 weeks gestation, without a history of respiratory symptoms or congenital abnormalities were studied on the postnatal ward of the Royal Sussex County Hospital, Brighton, UK.

Firstly, a FloRight vest of suitable size – fitting snugly but without constriction – was put on over a single thin layer of clothing. The correct size of vest was gauged by measuring the chest circumference at nipple level, and the vest was placed covering the infant from armpit to groin. In this position the junction between the upper and lower coils of the vest is approximately at the lower border of the ribcage. The FloRight system was calibrated with the magnetic field detector in place and the volume reference cylinder at the side of the infant. For measurement the magnetic field detector was positioned so that the vest was aligned with the two fins and equidistant between them, with the baby lying on a surface 40 cm below the fins. The EcoMedics system was calibrated with a 100 ml Hans Rudolph volumetric syringe (Hans Rudolph Inc, Shawnee, Kansas, US). Once the baby was in quiet natural sleep, a firm face mask with inflatable cushion rim was placed over the baby's nose and mouth, then collection of two minutes of tidal breathing data was commenced

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3 simultaneously with the two systems. These recordings will be designated V1 (FloRight vest)  
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5 and M1 (EcoMedics mask). The mask was then removed, and a two minute epoch of tidal  
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7 breathing was recorded using FloRight alone, with no mask in place – designated V1A .  
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10 Finally, a further two-minute epoch was recorded using both systems for repeatability  
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12 measurements – designated V2 and M2. Figure 1 shows the mask and vest in place  
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14 simultaneously during data collection. The data sampling frequency was 200 Hz for the  
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For calculation of the tidal breathing parameters, the traces were first inspected visually to select a 10-breath segment of stable tidal breathing with the following characteristics: no obvious artefacts, no sighs, no obvious changes in depth of breathing or baseline.

Simultaneous 10-breath segments from M1/V1, M2/V2, and from V1A were then analysed in detail to calculate the following parameters, measured breath-by-breath then averaged over the 10-breath segment:

1. Tidal volume ( $V_T$ ) in ml, and per Kg body weight ( $V_T/Kg$ )
2. Time to peak tidal expiratory flow as a ratio of expiratory time ( $T_{PTEF}/T_E$ )

For the vest recordings only, the following additional tidal parameters were calculated from the traces:

3. Ratio of expiratory time to inspiratory time ( $T_E/T_I$ )
4. Expiratory flow at 50% of tidal volume as a ratio of peak tidal expiratory flow  
 $(TEF_{50}/PTEF)^2$
5. Expiratory flow at 25% of tidal volume as a ratio of peak tidal expiratory flow  
 $(TEF_{25}/PTEF)^2$

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6. Centre of gravity along the volume axis for the tidal expiratory flow-volume curve (FVg). This is the dimensionless value along the volume axis (taking 0 as the start of expiration and 1 as the end of expiration) such that the areas under the curves to right and left of this point are equal. A symmetrical curve with peak flow occurring at mid-tidal volume would have  $FVg=0.5$ ; any shift of peak tidal expiratory flow towards the start of inspiration will give values below 0.5.

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The parameters were compared, using paired t-test and Bland-Altman analysis, between pairs of recordings as follows.

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M1 and V1 were compared to assess the validity of the FloRight vest measurements.

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M1 was compared with M2, and V1 with V2, to assess repeatability of both the mask and vest measurements.

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V1 was compared with V1A to assess the effect of a facemask on tidal breathing parameters.

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For the second part of the study, 11 oxygen-dependent infants with bronchopulmonary dysplasia (BPD, defined as persistent supplemental oxygen need beyond 36 weeks gestation, following neonatal respiratory failure) were measured, using the same protocol as above as far as possible. Mask measurements were not possible because of the nasal cannula oxygen (the oxygen flow caused a large baseline drift), so only V1 and V2 were recorded. The coefficient of repeatability of the vest measurements of tidal breathing parameters was calculated. In addition, the tidal measurements were compared with the 10 healthy term infants using two-sample t-tests.

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3 The characteristics of the infants studied are summarised in Table 1. Although the weight  
4 and length of the two groups is similar, the BPD infants, as would be expected, were short  
5 and light for age even when corrected for prematurity.  
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## 10 11 Results

### 12 13 Validity

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19 Figure 2 shows Bland-Altman plots of M1 vs V1 for  $V_T$  and for  $T_{PTEF}/T_E$ , with mean difference  
20 and limits of agreement shown. There was no significant difference in either parameter, and  
21 there was close correspondence between the paired measurements as shown by the small  
22 mean differences (Mask minus Vest  $V_T +0.096$  ml,  $T_{PTEF}/T_E -0.01$ ) and narrow limits of  
23 agreement ( $V_T +4.5$  ml to  $-4.3$  ml,  $T_{PTEF}/T_E +0.32$  to  $-0.35$ ).  
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### 32 33 Repeatability

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36 Repeatability was expressed as the coefficient of repeatability (CR), defined as twice the  
37 standard deviation of the differences between measurements<sup>11</sup>. We have also expressed it  
38 as a percentage of the mean value (CR%). Table 2 shows CR and CR% for: M1 vs M2 in  
39 healthy infants, V1 vs V2 in healthy infants, and V1 vs V2 in BPD infants.  
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### 46 47 Effect of facemask

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50 Table 3 shows mean difference, 95% confidence intervals of mean difference, and limits of  
51 agreement for the tidal parameters, comparing V1 with V1A in the healthy infants. Tidal  
52 volume is significantly higher with the mask in place, as would be expected because of the  
53 additional deadspace. However, there was no significant difference in any of the tidal  
54 expiratory flow parameters.  
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3 Changes with disease  
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7 Figure 3 shows typical flow-time and flow-volume traces recorded by the FloRight device in  
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9 a healthy infant and a BPD infant: a clear difference can be seen in the pattern of expiratory  
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11 flow (“sinusoidal” versus “quadrilateral” as originally described by Morris and Lane<sup>12</sup>). Table  
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13 4 shows mean difference and 95% confidence intervals of mean difference, comparing V<sub>T</sub> in  
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15 healthy infants with V<sub>T</sub> in BPD infants. There were significant differences in tidal volume  
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17 (corrected for body weight) and all tidal expiratory flow parameters. V<sub>T</sub> per Kg was  
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19 significantly higher in BPD infants (as expected due to increased physiological deadspace),  
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21 while all the tidal expiratory flow parameters were significantly lower. Ratio of inspiratory to  
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23 expiratory time (T<sub>I</sub> / T<sub>E</sub>) showed only a non-significant trend to be lower.  
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## 34 Discussion

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38 We have demonstrated that a novel volumetric vest system is able to measure both tidal  
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40 volume and tidal expiratory flow parameters in unsedated infants, without prior calibration  
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42 on the infant, and to yield values in healthy infants which are very close to those measured  
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44 directly from airflow at the airway opening. The measurements using the vest are as  
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46 repeatable as those measured at the airway opening. Furthermore, we have shown that  
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48 tidal measurements made using this system are able to differentiate infants with  
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50 bronchopulmonary dysplasia from healthy term infants.  
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56 Previous work using RIP has yielded conflicting results. Stick et al<sup>9</sup>, using uncalibrated RIP,  
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58 showed close agreement between T<sub>PTEF</sub>/T<sub>E</sub> values from RIP with those from mask and  
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60 pneumotachograph in unsedated healthy newborn infants. However, Jackson et al<sup>10</sup>, using

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3 a different uncalibrated RIP system in unsedated newborns and sedated older infants were  
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5 unable to replicate this. In their study, RIP-measured  $T_{PTEF}/T_E$  was consistently lower, with  
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7 wide limits of agreement. Neither study was designed to measure tidal volume.  
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11 Our values for tidal parameters in the healthy infants, measured both by mask and by vest,  
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13 are very similar to published values in healthy term neonates measured by mask<sup>13-15</sup>. This,  
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15 as well as our finding that tidal expiratory flow parameters (unlike tidal volume) were not  
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17 altered by the presence of a mask, suggests that existing normative values are appropriate  
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19 in interpreting measurements made using this vest system. Our figures for repeatability of  
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21  $T_{PTEF}/T_E$ , both with mask (CR 41%) and vest (CR 37%), are also similar to published values<sup>13</sup>,  
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23 and demonstrate how variable this parameter is in newborn infants. This is a significant  
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25 limitation of  $T_{PTEF}/T_E$ , however measured, and suggests that the parameters with better  
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27 repeatability such as FVg may be worth exploring .  
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35 Clearly caution is needed in applying our conclusions on the validity of the system. We were  
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37 not able to make mask measurements in our BPD infants because of the administration of  
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39 nasal cannula oxygen, and therefore were not able to show whether the Floright system  
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41 makes valid measurements in the presence of chest distortion. All our measurements were  
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43 made during spontaneous tidal breathing in infants lying supine, so that we cannot  
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45 comment on the validity of measurements in prone or side-lying infants, in older children  
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47 measured in a sitting position, or in artificially ventilated infants. All our healthy neonates  
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49 were above 2Kg weight: it is not yet clear whether the system will be accurate in small  
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51 preterm infants.  
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58 At the beginning of the study we encountered difficulty in calibrating the equipment in an  
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60 electrically “noisy” environment (eg near television screens): a software change was

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3 required to resolve this problem. Interference from nearby devices producing a high  
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5 frequency changing magnetic field may still cause problems, in some settings, but would be  
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7 likely to produce a “noisy” trace, rather than inaccurate measurements. The equipment is  
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9 currently large and cumbersome, making its use in acute or intensive care settings difficult:  
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11 we understand that design changes to modify this problem are planned.  
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17 Despite these caveats, our findings suggest that this is an accurate technique for measuring  
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19 tidal breathing without the need for a face mask. This technique has the potential to  
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21 measure tidal flow parameters in situations where a mask is not tolerated (eg tachypnoea,  
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23 awake infants) or mask measurements are problematic (eg oxygen therapy, continuous  
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25 positive airway pressure, non-invasive ventilation). The volume changes can also be  
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27 partitioned into chest and abdominal components, giving the potential to measure  
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29 thoracoabdominal asynchrony in the context of acute respiratory disease or sleep-  
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31 disordered breathing. Further work is needed to validate the technique in these settings.  
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Figure 1a: Study setup, showing both FloRight vest and mask with ultrasonic flowmeter in place. The two fins of the magnetic field detector are shown suspended above the infant.  
105x72mm (150 x 150 DPI)