

# The clinical evaluation of the Respi-check mask<sup>\*</sup>: a new oxygen mask incorporating a breathing indicator

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## Abstract

**Study objective**—To investigate the correlation between the Respi-check sensor and simultaneous chest auscultation in determining the respiratory rates in adults.

**Methods**—Random visits to a local accident and emergency (A&E) department were made and all patients wearing oxygen masks were recruited into the study. The new sensor was attached to the outside of the mask. One researcher auscultated the chest to count breaths, the other counted the sensor activity. Each was blinded to the activities of the other. Breaths were counted by each researcher simultaneously and independently over one minute. A total of 40 patients were recruited into the study. A difference of more than two breaths/min compared with chest auscultation was deemed as a sensor failure.

**Results**—The respiratory rates of 40 patients were measured. There were 28 men, 12 women. Twenty six patients were wearing an Intersurgical high concentration (flow 12l/min) mask, 14 were wearing an aerosol mask with variable venturi (flow 3–12l/min) by Medicaid. Over one minute rates determined by the two methods were the same in 28 cases (70%). It was accurate to within one breath in 37 cases (93%) and to within two breaths in 39 (98%) cases and in one case (2.5%) the sensor failed. The mean difference (mean of the differences between rates obtained from auscultation and the new sensor) was  $-0.1282$  breaths/min, with limits of agreement (d (2SD) between  $-1.414$  to  $1.157$  breaths/min.

**Conclusion**—The Respi-check sensor provides an accurate method of estimating the respiratory rate in adult patients attending the A&E department.

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The respiratory rate is one of the most important physiological parameters, being a component of most medical and nursing records and clinical scoring systems. Over the past decade scoring systems for trauma and critical illness such as TRISS<sup>1</sup> and APACHE II<sup>2</sup> have proliferated, driven by quality improvements and resource allocation and the need to establish a national standard for trauma outcome,

the UK Trauma Audit and Research Network (TARN) formerly MTOS. Evidence based medicine has seen an increase in clinical decision pathways with the respiratory rate playing a pivotal part in asthma and obstructive airway disease management plans.<sup>3</sup> The accuracy of the data depends on the diligent recording of the respiratory rate, which should ideally be counted over one minute.<sup>4</sup> Despite advances in pulse, blood pressure and oxygen saturation monitoring, visual observation alone is used to monitor the respiratory rate in clinical practice and this method is known to be highly inaccurate.<sup>5</sup>

The authors have designed a sensor that can be incorporated into any currently available oxygen mask. The sensor is a clear visual indicator of the patients respiratory activity and breathing pattern and together with an infrared electronic counter acts as a continuous, real time measure of physiological performance.

The objective of this study was to investigate the accuracy of the respiratory sensor in determining the respiratory rates in a population of accident and emergency (A&E) patients. Clinical accuracy was assessed by analysis of the



Figure 1 The Respi-check mask. The housing attached to the mask contains a coloured float that rises and falls in response to pressure and flow changes during breathing. The housing is designed to rotate through 360 degrees to allow monitoring in all positions.

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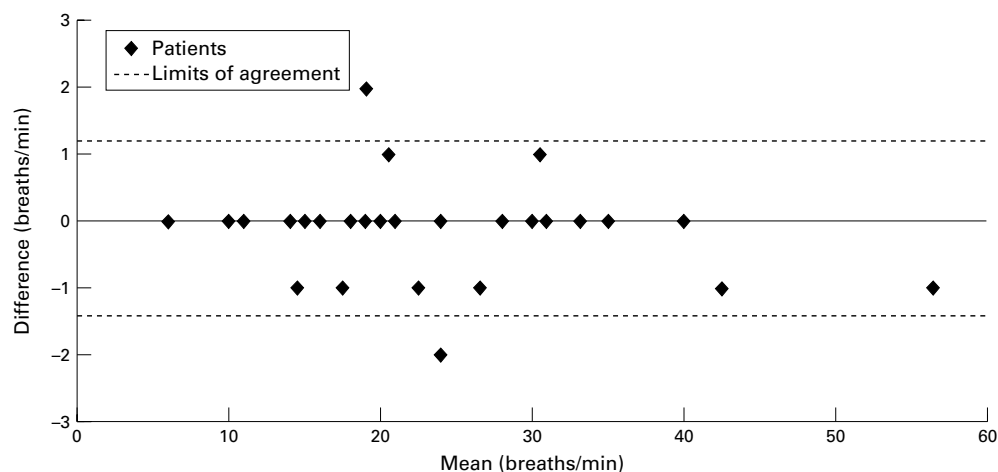


Figure 2 Mean breaths plotted against the difference between auscultation and the new sensor (breaths/min) in 39 A&E patients (there is overlap of some data).

differences between the respiratory rates determined using the sensor and those determined simultaneously by chest auscultation<sup>6</sup> in 40 patients. The mean of the differences ( $d$ ) between the rates was recorded by each method and the standard deviation was used to calculate the limits of agreement ( $d$  (2SD)).

We hypothesised that our respiratory rate sensor provides an acceptable method of recording the respiratory rate in the clinical setting.

### Methods

Random visits to a local A&E department were made and all patients wearing oxygen masks were recruited into the study. The department used two types of oxygen mask, the Intersurgical high concentration mask (12 l/min) and the Medicaid aerosol mask with variable venturi (3–12 l/min). No patients were excluded from the study. Patients were enrolled after written consent and the study was approved by the regional and local ethics committees.

The sensor comprises a clear plastic housing containing a lightweight, clearly visible float (fig 1). The housing has two arms at 90 degrees to each other, one arm in connection with the interior of the oxygen mask, the other with the atmosphere. The sensor can swivel through 360 degrees to allow for monitoring in all positions. The sensor was attached over one ventilation hole without occlusion. The sensor responds to changes in pressure and flow generated within the mask during respiration with movement of the lightweight float between two end stops. The movement of this float can be clearly seen and counted and our hypothesis that the float movement corresponds to each breath can be investigated. The mask was secured to the face as advised by the manufacturer's instructions and oxygen was given at a flow appropriate to the mask or mask with venturi. One researcher auscultated the chest for breath sounds while the other simultaneously and independently counted the sensor activity. Each researcher was blinded to the activity of the other. Respiration was counted over one minute. If the sensor recorded an error of more than two breaths over one minute compared

with auscultation this was recorded as a sensor failure. The Glasgow Coma Scores and the respiratory rates were recorded on individual patient data sheets. Limits of agreement were calculated according to the statistical clinical measurement comparison technique described by Bland and Altman.<sup>7</sup>

### Results

Forty patients were recruited into the study (28 men and 12 women). The men had an age range 28–87 (mean 61), respiratory rate range 6–57 breaths/min and a GCS range 6–15. The women had an age range 17–78 (mean 61), respiratory rate range 11–40 breaths/min and a GCS range of 3–15. Twenty six patients were wearing a high concentration mask (Intersurgical), while 14 patients were wearing the aerosol mask with venturi (Medicaid). The difference between the rates obtained by the two methods were calculated. The sensor correlated precisely with auscultation in 28 patients (70%), there was one breath difference in nine patients (22.5%) and two breaths difference in two patients (5%). In one patient the sensor failed (2.5%). We plotted the differences between rates obtained by auscultation and the new sensor against the mean of the difference between the two measurements (fig 2). The mean difference ( $d$ ) was  $-0.128$  breaths/min. The limits of agreement ( $d$  (2SD)) as described by Bland and Altman<sup>7</sup> ranged from  $-1.414$  to  $1.157$  breaths/min.

### Discussion

This study shows the close agreement between the rates obtained using the new sensor and those from chest auscultation in a random population of adult A&E patients receiving oxygen treatment. Ninety three per cent of the respiratory rates recorded by our new sensor were within one breath of the corresponding auscultation rate, and the limits of agreement were within two breaths. The new sensor is simple to use, inexpensive, non-invasive (mask mounted), disposable, safe, accurate and reproducible. An electronic counter can be attached to the sensor to provide a continuous

respiratory rate record throughout the monitoring of acutely ill patients. The accuracy of the electronic counter was not investigated in this study.

As with any clinical sensor there are disadvantages and limitations that should be recognised. The respiratory sensor is mask mounted and therefore limited to those wearing oxygen masks. It is maximally sensitive when the mask to face seal is good and incidentally our sensor indicates this visually. A combination of poor mask to face seal (cachexia or small face) and poor respiratory effort will result in the sensor failing and this happened in one patient during our study. With a clear visual indicator of failure by this method—that is, the float not moving—alternative methods would need to be used if respiratory rate monitoring was essential. We anticipate the sensor to have the same accuracy in the paediatric population, and this is under investigation.

The accurate recording of the respiratory rate is an essential part of the evaluation of the acutely ill patient. The pattern and depth of respiration should also be noted during the clinical examination. Alveolar ventilation is assessed by depth and respiratory rate (depth  $\times$  rate = alveolar ventilation) and differentiates the pharmacological effects of sedatives (rapid shallow breaths) from opioids (slow deep breaths) during their misuse. In comatose patients abnormalities occur in both the rate and pattern of respiration. Cheyne-Stokes respiration produces periodic breathing with a crescendo-decrescendo pattern of rate and depth. Measurement of inspiratory and expiratory phases highlight apneustic respiration by infrequent, deep inspiration with a prolonged inspiratory hold. This usually indicates a pontine lesion, but has been reported with hypoglycaemia, anoxia and meningitis. The phases of respiration yield information during assessment of airflow obstruction in acute asthma and together with the PEF<sub>r</sub> and FEV<sub>1</sub> help to plan treatment and assess progress.

Current methods used in emergency medicine for monitoring the respiratory rate include capnography and thoracic impedance plethysmography. Both methods are in use, but have limitations in clinical practice.

Capnography has been in use since the 1950s. Its role in the intubated patient is unquestionable, but in the non-intubated patient the role is less clear. For non-intubated patients capnometers use a sidestream sampler or a nasal cannula. The sidestream tubing is small and may become blocked with water vapour introducing error.<sup>8</sup> The nasal cannula method has been used by researchers<sup>9</sup> who found problems recording during episodes of tachypnoea and problems from nasal obstruction in patients with excess secretions. The advantages of the capnogram in the emergency room include verification of the endotracheal tube placement, the use of pulmonary end tidal carbon dioxide (PETCO<sub>2</sub>) to estimate PaCO<sub>2</sub>, indication of adequate cardiopulmonary resuscitation and possible waveform analysis in patients with obstructive airway disease (phase

III slope correlation with FEV<sub>1</sub>).<sup>8</sup> Future uses of PETCO<sub>2</sub> may help in the diagnosis of pulmonary embolus and in the non-invasive measurement of cardiac output.<sup>10</sup> One drawback for PETCO<sub>2</sub> monitoring is the finding that PETCO<sub>2</sub> is less accurate in estimating the PaCO<sub>2</sub> with tidal volume breathing and in patients with pulmonary disease.<sup>11</sup> Capnography equipment is delicate, expensive and requires calibration, further factors that limit its widespread use.

In the 1990s ECG monitors arrived on the market that detected respiration through trans-thoracic impedance. They had the advantage of simplicity and were recommended for introduction into clinical practice.<sup>12</sup> The problems associated with impedance in clinical practice were extreme sensitivity to movement and a poor quality respiratory trace and although not universal they are in use in a number of A&E departments in the UK.

During the 1980s and 1990s researchers continued their search for a simple, non-invasive respiratory rate monitor. Methods included the Aberdeen University Respiratory Alarm (AURA)<sup>13</sup> using polyvinylidene film strips mounted inside a mask, an acoustic airflow sensor,<sup>14</sup> a rapid response hygrometer,<sup>15</sup> fibreoptic sensors<sup>16,17</sup> and a nasal thermocouple.<sup>18</sup>

A number of these innovations are in use in clinical practice. The nasal thermocouples are used in sleep studies and fibreoptic sensors have been used to measure the respiratory rate in patients during magnetic resonance scanning, but none have found a place in routine monitoring on hospital wards or the A&E department.

Our respiratory sensor can be used to monitor adult patients in a multitude of hospital and prehospital care settings. An increase in the use of helicopters for patient transport has its own unique problems<sup>19,20</sup> and a simple indicator of respiratory rate or apnoea would be a valuable tool. Commercial airlines may consider using the sensor for in flight care when oxygen treatment is being given in the emergency situation.

In conclusion, the accurate recording of the respiratory rate is an essential part of the evaluation of the acutely ill patient. The new respiratory sensor demonstrated close agreement with chest auscultation in determining the respiratory rate over one minute in a population of 40 acutely ill patients attending an emergency department. The mean of the differences (d) between the two methods was  $-0.128$  breaths/min with limits of agreement (d (2SD)) of  $-1.414$  to  $1.157$  breaths/min. These findings suggest that the Respi-check breathing sensor used in this study provides an accurate means of determining the respiratory rate in adults.

#### Contributors

Andrew Breakell designed the study hypothesis and coordinated the clinical research, carried out literature searches, data collection, result interpretation and writing the paper. Chris Townsend-Rose designed the study hypothesis, coordinated the clinical research, carried out literature searches, data collection, result interpretation and editing the paper. Simon Fear provided statistical guidance for the study.

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Conflicts of interest: the product was designed by the authors and registered for a world patent application. The product is currently being manufactured under licence to a British company.

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- 1 Boyd CR, Tolson MA, Copes WS. Evaluating trauma care: the TRISS method. Trauma Score and the Injury Severity Score. *J Trauma* 1987;27:370–8.
- 2 Knauss WA, Draper EA, Wagner DP. APACHE-II: a severity of disease classification system. *Crit Care Med* 1985;17:305–8.
- 3 The British Thoracic Society, The National Asthma Campaign, The Royal College of physicians of London in association with the General Practitioner in Asthma Group, The British Association of Accident and Emergency Medicine, The British Paediatric Respiratory Society and The Royal College of Paediatrics and Child Health. The British Guidelines on Asthma Management 1995 Review and Position Statement. *Thorax* 1997;52 (suppl 1).
- 4 Rosen P, Barkin R. *Emergency medicine concepts and clinical practice*. 4th ed. St Louis: Mosby, 1998:2110–11.
- 5 Krieger B, Feinerman D, Zaron A, et al. Continuous non-invasive monitoring of the respiratory rate in critically ill patients. *Chest* 1986;90:632–4.
- 6 Mower WR, Sachs C, Nicklin EL, et al. A comparison of pulse oximetry and respiratory rate in patients screening. *Resp med* 1996;90:593–9.
- 7 Bland M, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986;i:307–11.
- 8 Murphy M. Monitoring the emergency patient. In Rosen P, Barkin R. *Emergency medicine concepts and clinical practice*. 4th ed. St Louis: Mosby, 1998:119–23.
- 9 Egleston CV, Aslam B, Lambert M. Capnography for monitoring non-intubated spontaneously breathing patients in an emergency room setting. *J Accid Emerg Med* 1997;14:222–4.
- 10 Ward KR, Yealy DM. End-tidal carbon dioxide monitoring in emergency medicine, part 2: clinical applications. *Accid Emerg Med* 1998;5:637–46.
- 11 Plewa MC, Sikora S, Engoren M, et al. Evaluation of capnography in non-intubated emergency department patients with respiratory distress. *Acad Emerg Med* 1995;2:901–8.
- 12 Clancy MJ, Williams MJ. The respiratory rate. *Arch Emerg Med* 1991;8:222.
- 13 Kulkarni V, Cyna A, Huchison JM, et al. AURA: a new respiratory monitor. *Biomed Sci Instrum* 1990;26:111–20.
- 14 Hok B, Wiklund L, Henneberg S. A new respiratory rate monitor: development and initial clinical experience. *International Journal of Monitoring and Computing* 1993;10:101–7.
- 15 Tatara T, Tsuzaki K. An apnoea monitor using a rapid-response hygrometer. *J Clin Monit* 1997;13:5–9.
- 16 Davis C, Mazzolini A, Murphy D. A new fibre optic sensor for respiratory monitoring. *Australas Phys Eng Sci Med* 1997;20:214–19.
- 17 Vegfors M, Ugnell H, Hok B, et al. Experimental evaluation of two new sensors for respiratory rate monitoring. *Physiol Meas* 1993;14:171–81.
- 18 Marks MK, South M, Carter BG. Measurement of respiratory rate and timing using a nasal thermocouple. *J Clin Monit* 1995;11:159–64.
- 19 Hunt RC, Bryan DM, Brinkley VS, et al. Inability to assess breath sounds during air medical transport by helicopter. *JAMA* 1991;17:1982–4.
- 20 Pollution TJ, Worthington DW, Passaic TR. Physiologic chest sounds and helicopter engine noise. *Aviat Space Environ Med* 1994;65:338–40.