A novel, contactless, portable "spot-check" device accurately measures respiratory rate

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Abstract

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Background:

Respiratory rate (RR) is an important vital sign used in the initial and ongoing assessment of acutely ill patients. It is also used as a predictor of serious deterioration in a patient's clinical condition. Convenient electronic devices exist for measurement of pulse, blood pressure, oxygen saturation and temperature. Although devices which measure RR exist, none has entered everyday clinical practice.

Objectives:

We have developed a contactless portable respiratory rate monitor (CPRM) and evaluated the agreement in respiratory rate measurements between existing methods and our new device. The CPRM uses thermal anemometry to measure breath signals during inspiration and expiration.

Method:

RR data were collected from 52 healthy adult volunteers using respiratory inductance plethysmography (RIP) bands (established contact method), visual counting of chest movements (established non-contact method) and the CPRM (new method), simultaneously. Two differently shaped funnel attachments to the CPRM were evaluated for each volunteer.

Results:

Data showed good agreement between measurements from the CPRM and the gold standard RIP, with intra-class correlation coefficient (ICC): 0.836, mean difference 0.46 and 95% limits of agreement of -5.90 to 6.83. When separate air inlet funnels of the CPRM were analysed, stronger agreement was seen with an elliptical air inlet; ICC 0.908, mean difference 0.37 with 95% limits of agreement -4.35 to 5.08.

Conclusions:

A contactless device for accurately and quickly measuring respiratory rate will be an important triage tool in the clinical assessment of patients. More testing is needed to explore the reasons for outlying measurements and to evaluate in the clinical setting.

Introduction

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The measurement of a patient's vital signs including heart rate, temperature, blood pressure and respiratory rate is routine practice to all those who attend emergency departments. The National Institute for Clinical Excellence (NICE) recommends that these signs are recorded for all children presenting with a fever [1]. Respiratory rate (RR) is important in helping to guide clinicians to assess and classify patients and also to identify those who are at risk of deteriorating [2]. However of the four vital signs, respiratory rate appears to be the least often recorded and most often completely omitted from hospital documentation [3, 4].

Respiratory rate measurement in the emergency department, unlike other vital signs, relies solely on a subjective assessment. The current World Health Organisation standard for respiratory rate measurement is a count over a full minute by observing abdominal and chest movements or by auscultation [5]. Both methods have been shown to give similar results [6]. In practice it is usual for a direct observation of respirations to take place over a shorter period of 15 or 30 seconds and then multiplied by a factor of 4 or 2 to calculate the breaths per minute. This however has been shown to lead to inaccuracies [7]. Inconsistencies in respiratory rate measurement can also come from inter-observer variability. Generally good agreement has been shown between observers measuring an adult's respiratory rate [8, 9]. However single respiratory rate measurements were shown on occasions to wrongly classify patients as being more or less unwell than they actually were, therefore potentially affecting their assessment and subsequent management [10].

There are convenient electronic devices for the measurement of many of the vital signs. Not only do these provide accurate measures, they also provide healthcare professionals with a prompt. Although devices for measuring respiratory rate exist, they are used mainly in the intensive care, post-operative or sleep study setting, none have entered everyday clinical practice in the acute assessment of patients. Many of these devices require body contact, [11-13] which may not be practical and could be distressing to the patient, inadvertently increasing their RR. Non-contact devices have also been developed but can require complex equipment, [14] be expensive to use

and set up and impractical for most clinical settings [15, 16. Others are still in a developmental phase and require further clinical validation [17]

Our aim is to produce a contactless "spot-check" method of measuring respiratory rate in children. The aim of this study was to validate the method in adult volunteers prior to testing with children. The contactless portable respiratory rate monitor (CPRM) device uses a self-heating thermistor housed within a handheld device, held a short distance from the subject's face. The temperature of the thermistor is modulated by the subject's breath producing a signal that fluctuates as air is inhaled and exhaled. Along with this, two different funnels attached to the CPRM were trialed for accuracy. The new method was compared against standard contact and clinical methods of measurement.

Methods

Study design and setting

We enrolled a convenience sample of 52 healthy adult volunteers from two locations, Sheffield Hallam University and Sheffield Children's Hospital between July and September 2014. The study was approved by the regional ethics committee and written consent was obtained from each individual prior to participation. All recordings were performed in a room with temperature about 25°C. Humidity was not measured as the device is not susceptible to a typical humidity level encountered in its operational environment, although extreme humidity may interfere with its sensor (a self-heating thermistor, details included in the section describing the device). As the sensor's reference temperature was 40°C, while the room temperature where the recording is performed remains below this reference temperature, the device functions correctly.

Methods of measurements

The respiratory rate of each participant was measured simultaneously by three different methods. Respiratory inductance plethysmography (RIP) was used as the established contact method and gold standard. Visual counting of chest movements represented the established non-contact method, and method used in most clinical settings. The contactless portable respiratory rate monitor (CPRM), our new method, was the experimental method. Three to four data sets were collected for each participant.

Contactless portable respiratory rate monitor (CPRM):Figure 1 shows the CPRM device. Respiratory airflow is detected by a self-heating thermistor. The thermistor's temperature without respiratory airflow is maintained at around 40°C, i.e. its reference temperature. Respiratory air flow during exhalation causes a reduction in the thermistor's reference temperature and during inhalation the thermistor's temperature recovers (due to its self-heating feature) back toward its reference value. In this mode of operation, the self-heating thermistor is not measuring the expired air warmth but the airflow caused by it. The fluctuations in the thermistor's temperature produce an

analogue signal that is in synchronization with respiration. The output analogue signal is amplified, digitized and read by a microprocessor. The microprocessor, attached to a small display screen, performs the necessary control of the recording and calculation of respiration rate.

In order to perform a recording, the air inlet of the device was held in front of the subject's face at a distance of 20 - 30 cm and on observing a respiratory signal on the device's screen, its trigger button was pressed. This initiated the data recording. The angle and exact position of the air inlet of the device in relation to the subject's face varied to an extent depending on the individual. The respiratory signal on the device's screen was a guide and on picking a recognizable respiratory signal the recording was commenced. The display of the respiratory signal continued for the duration of the recording.

On completion of the recording, the data are stored and a blip is heard. The respiration rate is then displayed in breaths per minute on the device's screen. A respiratory signal obtained using the device and its associated magnitude frequency spectrum are shown in Figures 2a and 2b respectively. To determine the respiration rate, the frequency associated with the dominant peak (highlighted by an arrow in Figure 2b) in the magnitude frequency spectrum of the respiration signal is determined and then its value is multiplied by 60. The frequency associated with the identified peak represents respiration rate in breaths per second, thus its multiplication by 60 ensures the value is expressed in breaths per minute.

The frequency domain approach for determining respiratory rate was chosen due to its robustness and the ease with which it could be implemented. The time domain approach for determining respiration rate requires measuring the number of cycles in the respiratory signal. As the shape (including its amplitude) of the respiratory signal can vary substantially over time and in different individuals, this approach was not used as it was considered to be less reliable than the frequency domain approach.

For the adapted frequency domain approach, the dominant peak in the magnitude frequency spectrum was identified by an algorithm that initially compared the magnitudes (vertical axis)

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associated with the first two frequencies (horizontal axis) in the spectrum. It stored both the frequency associated with the larger magnitude and the actual magnitude. The stored magnitude was then compared with the magnitude associated with the next frequency and if this frequency corresponded with a larger magnitude, the values of the stored frequency and magnitude were replaced with the updated values. This operation continues to the last frequency, resulting in the identification of the largest peak and its associated frequency.

The sample rate for signal recording was 20 samples per second and the recording duration was 52 seconds, resulting in 1040 samples. To obtain the magnitude frequency spectrum of the signal, fast Fourier transform (FFT) was performed by the device's microprocessor on the first 1024 samples. For FFT to be applicable the number of signal samples needs to conform to 2^k, where k is an integer number (k=10 in this study).

Funnels:

All measurements using the CPRM were completed with two different detachable air inlet funnels: one with a circular air inlet (inside edge D=80mm; radius=40mm, internal surface area of the opening 5281.02mm^2) and one with an elliptical inlet (Width at widest point=55mm; length at longest point=115mm, internal surface area of the opening 4877.32mm^2). Airflow modelling pointed to these two shapes as being the most suitable (Figure 3).

Respiratory inductance plethysmography (RIP):

Thoracic and abdominal respiratory inductance plethysmography bands (zRIP inductance effort belts) were used to capture and record respiratory signals from the participants. Data was recorded on the SOMNOtouch RESP portable screening device (S-Med, Birmingham, UK) and downloaded for visual analysis. To determine the RIP respiratory rate, the number of observed respiration cycles from this respiratory signal was counted manually during the time period at which the simultaneous measurements were taken.

The visual counting method

Visual counting of respiratory rate was performed by an independent experienced medical clinician separate from the person operating the CPRM. A count of observed chest movements over the same time period as the other measurements were being taken was made.

Data collection and procedure

Each participant was assigned a unique identifying number based on the order that they were recruited. Data on the participant's age and sex were collected. At a defined starting time the respiratory rate was simultaneously taken by each of the three methods for a period of 52 seconds. All measurements were taken simultaneously. All measurements were converted to breaths per minute and were entered into an Excel spreadsheet.

Statistical analysis

All results were analysed using SPSS© statistical analysis package. The pairwise agreement between RR counts from each of the three methods was assessed by Lin's concordance correlation and intra-class correlation coefficients with 95% confidence intervals. The differences between data sets were also charted using Bland-Altman plots. [18]

Results

<u>Study subjects</u>

A total of 166 respiratory rate measurements were made on 52 healthy subjects. Participant ages ranged from 20 to 52 years, with a median age of 31 years. 28 subjects were male (54%).

<u>CPRM compared with standard contact method</u>

When the CPRM was compared with RIP measurements the correlation was high (Intra-class correlation coefficient: 0.836; 95% CI 0.783 - 0.877). Figure 4a shows the scatterplot of the correlation between CPRM and RIP measurements.

Bland-Altman plots assessed the pairwise agreement between measurements by analysing the mean difference and standard deviation of the difference (Figure 4b). The mean difference was 0.46 with 95% limits of agreement of -5.90 to 6.83. This suggests that the CPRM may read up to 7 breaths/min above and 6 breaths/min below the RIP method.

<u>CPRM compared with visual counting method</u>

The CPRM showed a high correlation when compared with the established visual counting method (Intra-class correlation coefficient: 0.887; 95% CI 0.839 - 0.921) (Figure 5a). The mean difference was -0.64 with 95% limits of agreement of -5.78 to 4.50 (Figure 5b).

<u>Analysis of CPRM funnels</u>

Data was also analysed separately for each air inlet funnel. The funnel with the elliptical inlet showed a higher correlation with both RIP and standard visual counting methods. The funnel with the circular inlet, when compared with RIP measurements, had an ICC of 0.794 (95% CI :0.709 - 0.856) with a mean difference of 0.52 and 95% limits of agreement -6.72 to 7.76. The funnel with

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the elliptical inlet had an ICC of 0.908 (95% CI: 0.853 - 0.943). The mean difference was 0.37 with 95% limits of agreement -4.35 to 5.08 indicating that the elliptical inlet was more effective in guiding expired air into the device.

Discussion

This study has successfully measured the respiratory rates of healthy adult volunteers using a novel, contactless, portable, respiratory rate monitor. The CPRM is well tolerated by the participants, it was easy to use and there was minimal set up required. There was a strong correlation between the measurements from our CPRM device and that of the gold standard contact method (RIP) and also the standard clinical method of visual counting of breaths. When taking into account the shape of the air inlet funnel an even stronger correlation was observed with the funnel that had an elliptical upward pointing air inlet.

Currently, devices to measure respiratory rate exist [19], but none have made their way into the everyday clinical environment. Contact devices measuring thoracic impedance have had mixed results when taken out of a controlled environment [20, 21]. When applied to the acute setting thoracic impedance measurements of adults presenting to an emergency department showed poor agreement against criterion standard measurements of respiratory rate, [20] with the limits of agreement between -8.6 and 9.5 breaths/min. More recently acoustic methods of measuring RR have been trialed in children post-operatively [22]. When compared against capnography measurements, the limits of agreement were -7.3 to 6.6 breaths/min. Both methods show much wider limits of agreements than those demonstrated with our device. Also, unlike the CPRM device, these methods require equipment to be placed on the patient and as such may not be well tolerated, or even distort the RR measurements in some clinical settings and certain patient groups, including children.

Contactless devices have also been produced using a variety of different methodologies. Droitcour *et al*. [15] developed a low powered Doppler radar system. They compared measurements of RR in 24 hospitalised adults against a standard contact method and showed 95% limits of agreement between −4.5 and 1.8 breaths/minute. Niesters et al [23] developed a device that is placed within a facemask and measures the humidity of exhaled air to derive a RR. In 28 healthy adults they found

close agreement when compared with capnometry measurements with limits of agreement of −1.08 and 1.29 breaths/minute. Although appearing to show good accuracy such devices are limited by either long set up times, the requirement for expensive equipment or co-operation of the patient. As such these methods may not be appropriate for common clinical settings where a quick accurate RR measurement is required.

Lim et al [9] assessed the RR measurements taken twice during clinical assessment of 245 adult patients by the same and different observers. They showed 95% limits of agreement between -4.86 - 4.94 breaths/min for the same observer and -5.7 - 5.7 breaths/min for different observers. Based upon this data 95% limits of agreement for a RR measurement should be less than ±4 to ±6 breaths/minute. We have shown that the CPRM can measure within this level of acceptability and as such offers a viable method of measuring RR. The CPRM also shows a level of accuracy greater than that seen in other devices that have been brought into clinical practice. The infrared tympanic membrane thermometer as compared with axillary thermometry showed a correlation coefficient of 0.697 [24]. We have demonstrated a greater correlation when comparing the CPRM with both the gold standard contact method and visual counting method (ICC: 0.836 - 0.887).

The current CPRM is designed for short duration "spot-check" RR measurements in accident and emergency departments, doctor's surgeries, ambulances and home use. It is not designed for continuous respiration recording. There are some limitations to the device. It currently requires 52 seconds of data recording to analyse and measure the subject's RR. This may be too long in a clinical triage or ward setting. Increasing the recording duration makes is less tolerable to patients, especially children, and reducing the recording duration reduces the device's accuracy. The 52 second recording was a compromise between the two issues. Modifications are already ongoing to reduce the data recording time without compromising the accuracy of measurements. Deviations from ambient room temperature unless quite large (e.g. more than 10 degrees) have no effect on the device's operation and accuracy. Readings are also affected by large head movements of the individual, causing some breaths not to be measured, and this accounts for some of our outlying

measurements. If the device is positioned outside its operating range, i.e. about 30 cm from the face, the detected respiration signal can become too weak to detect. As the signal is displayed in real-time on the device's display, its user can slightly adjust the position of the device in relation to the face to ensure the respiration signal is visible on the device's screen and then activates the device for measurement. Funnels were utilized to improve the capture of exhaled air. They provided some tolerance with regard to head moments. Improvements have already been made to the signal processing algorithm since previous testing of the device (25). We are currently working on enhancing the operation of the device so that it incorporates automated signal gain control and signal strength indicator and improvements to the air inlet funnel. These will overcome some of the limitations of the existing version of the CPRM.

Conclusion

Respiratory rate is no less valuable than any of the other vital signs and has been shown to be a more sensitive predictor of clinical deterioration. However, the accuracy of its measurement falls behind. Whilst medical devices should not replace a clinician's assessment, a device that accurately measures and reminds clinicians to take a respiratory rate will be of great significance. Results obtained from our contactless respiratory rate monitor are extremely encouraging. It offers a method for quick and accurate respiratory rate measurements that could be valuable in the triage and ward settings. The portable and contactless nature of the device also makes the CPRM an ideal device for measuring RR in children. We have proven its accuracy in a controlled environment with healthy adult volunteers. Testing on different patient groups, including children is planned to further assess the accuracy and robustness of this novel device in clinical practice.

Funding

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Figure Caption List

Figure 1 - The contactless portable respiratory rate monitor (CPRM); interface unit.

Figure 2a - A respiratory signal obtained using the CPRM

Figure 2b - Magnitude frequency spectrum for the respiratory signal shown in Figure 2a.

Figure 3a - Funnel with circular air inlet.

Figure 3b - Funnel with elliptical air inlet.

Figure 4a: Scatterplot of correlation between CPRM and RIP respiratory rate measurements. Correlation coefficients also shown.

Figure 4b: Pairwise agreement between CPRM and RIP. The x axis represents the mean values of the two measurements and y axis the difference between the two readings. The solid line shows the mean bias and the dashed lines the 95% CI based on the standard deviation of the distribution.

Figure 5a: Scatterplot of correlation between CPRM and visual counting method. Correlation coefficients also shown.

Figure 5b: Pairwise agreement between CPRM and visual counting method. The solid line shows the mean bias and the dashed lines the 95% CI based on the standard deviation of the distribution.

Figure 1 - The contactless portable respiratory rate monitor (CPRM); interface unit.
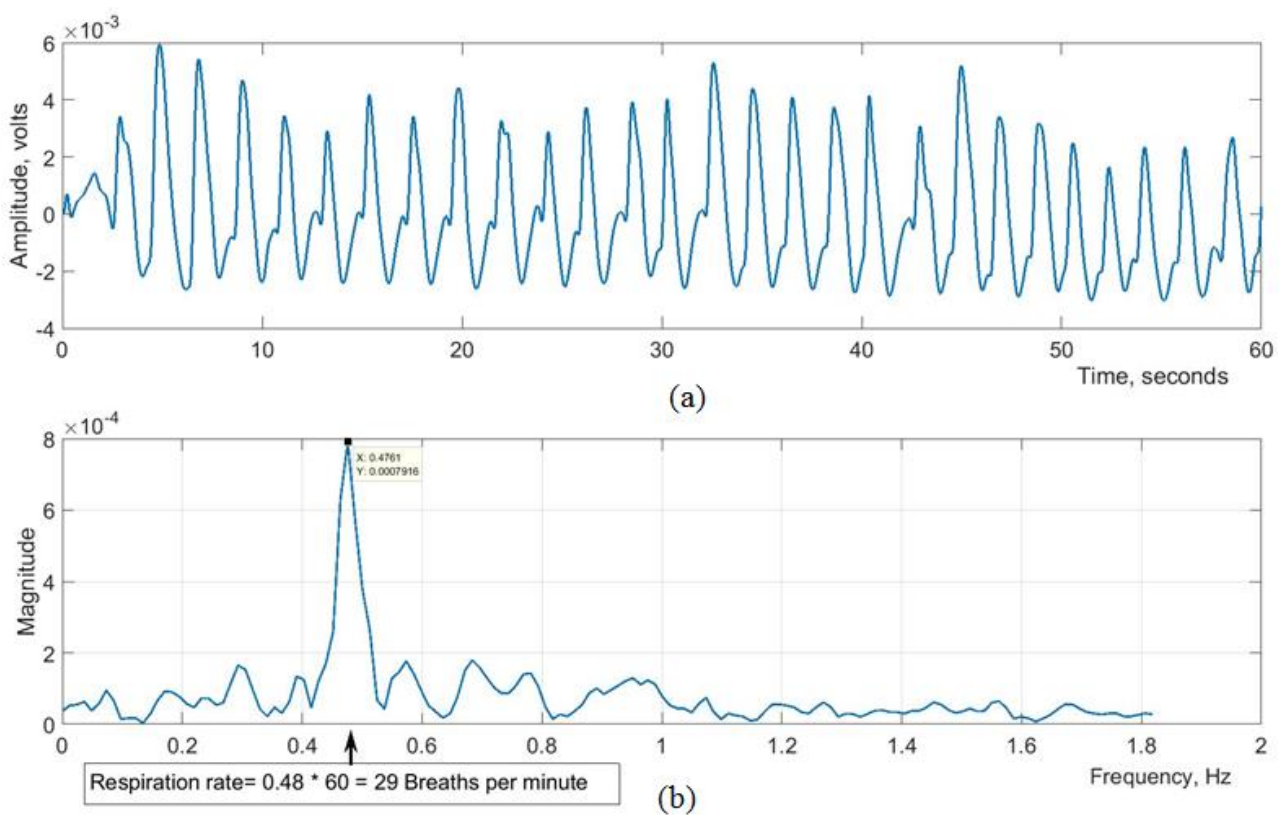

Figure 2 a - A respiratory signal obtained using the CPRM, b - Magnitude frequency spectrum for
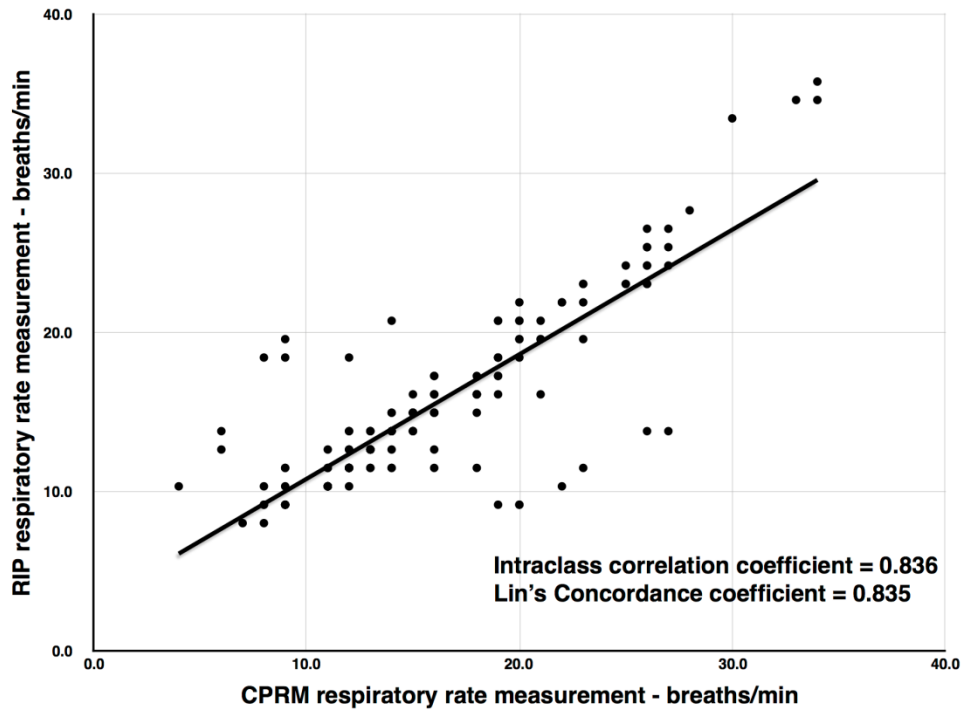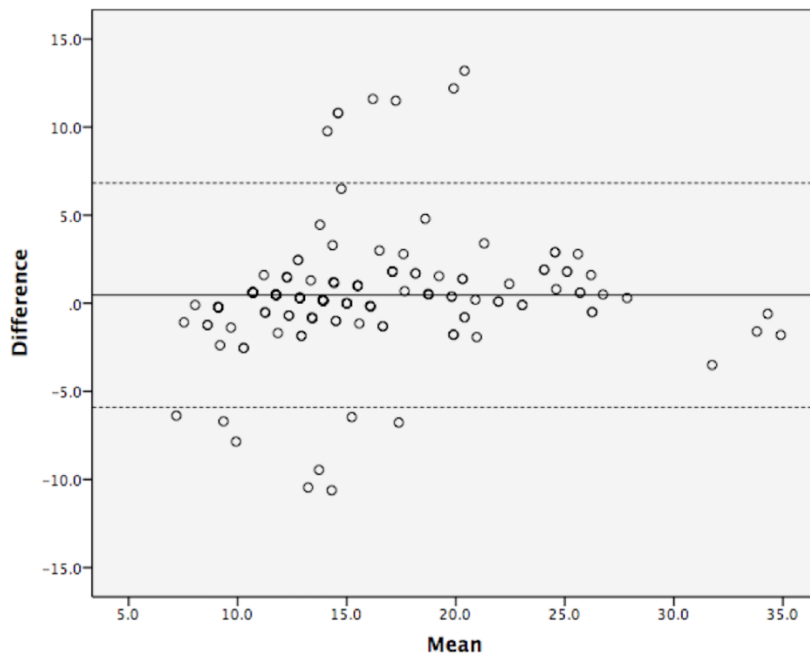
the respiratory signal shown in Figure 2a.

(a)

(b)

Figure 3 a - Funnel with circular air inlet., b - Funnel with elliptical air inlet.
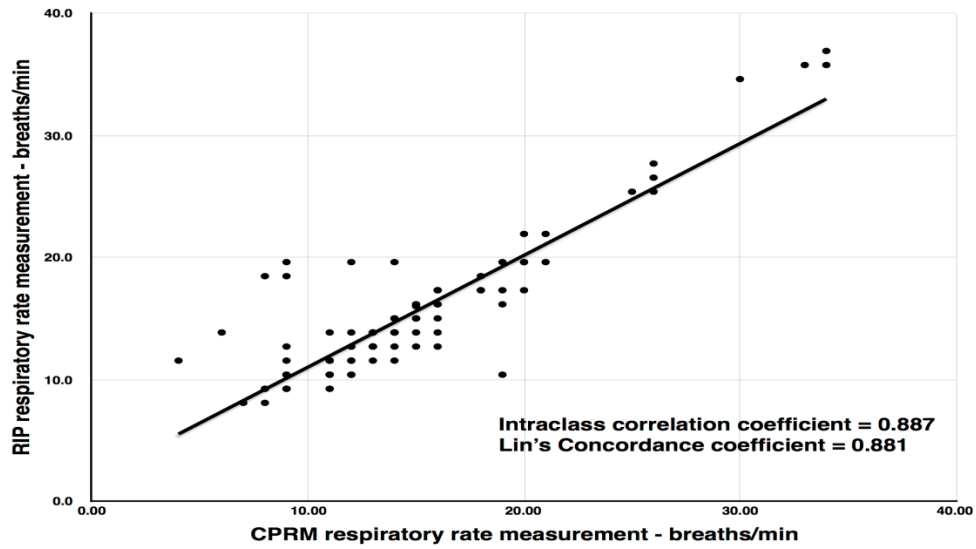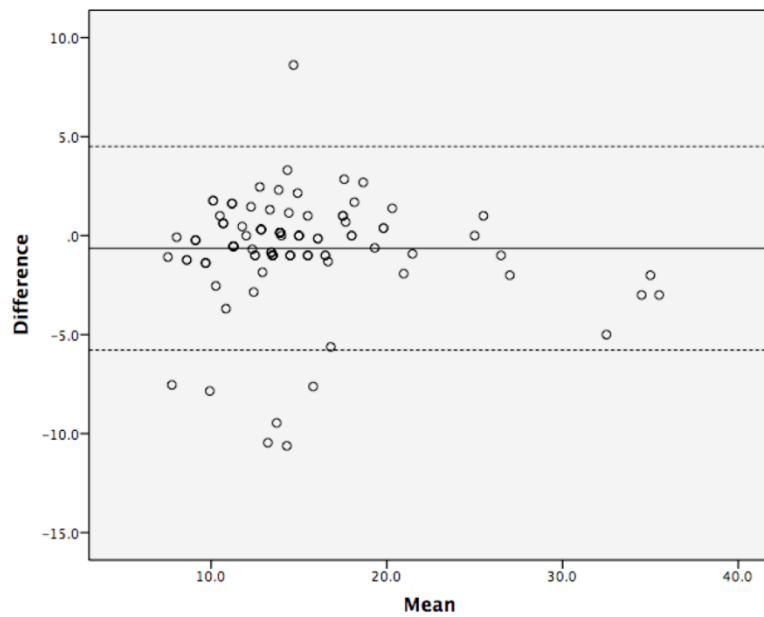
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(a)

(b)

Figure 4   a: Scatterplot of correlation between CPRM and RIP respiratory rate measurements. Correlation coefficients also shown, b: Pairwise agreement between CPRM and RIP. The x axis represents the mean values of the two measurements and y axis the difference between the two readings. The solid line shows the mean bias and the dashed lines the 95% CI based on the standard deviation of the distribution.

(a)

(b)

Figure 5   a: Scatterplot of correlation between CPRM and visual counting method. Correlation coefficients also shown, b: Pairwise agreement between CPRM and visual counting method. The solid line shows the mean bias and the dashed lines the 95% CI based on the standard deviation of the distribution.

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