WHITEPAPER

FLOW SENSOR WITH CO_2 SAMPLING PORT

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ABSTRACT

The clinical benefits and technical challenges in combining tidal flow-volume and carbon dioxide monitoring in the smallest neonatal patients are introduced. The features of a combination neonatal flow sensor with integrated respiratory gas sampling port are highlighted and its performance characteristics are demonstrated. An example conventional prior art flow sensor connected with a sidestream sampling adapter has a combined deadspace of 2ml and produces 7% tidal volume inaccuracy and a 12% false leak measure, when ventilating a 4ml tidal volume. The error further affects lung compliance, airway resistance and metabolic rate calculation errors. By comparison, the combination flow sensor with an integrated sidestream port has a deadspace of 0.8ml and it secures accurate tidal volume, leak, compliance and resistance values. The combination device can be used with sidestream CO_2 analysers that have sampling gas flow rates up to 150 ml/min.

INTRODUCTION

The global developments in respiratory care equipment focus largely on the adult care requirements. The requirements for neonatal care have tended to become appended as a technology scaling activity. However, certain technical performance characteristics translate poorly from the adult to the neonatal operating range. This has led to divergences in the state-of-art in two key patient monitoring technologies.

Table 1: Prevailing monitoring technologies

Monitoring	Adult care	Neonatal care
Tidal flow	Pressure differential, remotely measured	Hot wire anemometry, proximally measured
Tidal CO_2	Mainstream capnometry	Sidestream capnometry

Neonatal respiratory care is largely an output driven therapy, which means that input parameters are adjusted according to the physiological response they produce. There is no hard and fast rule for prescribing a set tidal volume in neonates. There is, however, evidence for synchronised ventilation that 'gently' provides a minimal necessary tidal volume resulting in lower mortality rates, compared with other invasive ventilation techniques [1]. Synchronised Volume Targeted Ventilation (VTV) also reduces the risk of bronchopulmonary dysplasia (BPD), pneumothorax and the number of days on invasive ventilation [1].

Best practice clinical protocol recommends a tidal volume between 4 and 8 ml/kg of ideal body weight [2]. This amount can vary dynamically as the patient condition changes during a care session. In order to secure low latency, flow triggered ventilator synchronisation with the onset of spontaneous efforts in the very smallest patients, the sensor should be capable of measuring flow rates as low as 0.2 l/min (smaller is better).

Synchronised ventilation that 'gently' provides a minimal necessary tidal volume results in lower mortality rates.

Such sensitivity, with accuracy, is unachievable using the pressure differential pneumotachograph that prevails in adult care. The small flow-volume measurements, in association with the airway pressure cycle, are further used in calculating and informing the lung compliance and airway resistance.

Best practice clinical protocol prescribes "crucial" carbon dioxide (CO_2) monitoring during neonatal ventilation [2]. Excessive CO_2 affects cerebral blood flows and is associated with adverse neurodevelopmental outcomes [2]. The conventional practice is to measure arterial CO_2 ($PaCO_2$) through multiple daily blood gas analyses. Although this is the most accurate method for measuring CO_2 levels, the invasive procedure has several drawbacks and risks in neonatal care. Catheter insertion has increased risks of infection and thrombosis [3]. Neonates have low blood volumes. Repeated sampling can lead to anaemia and the requirement for risky blood transfusions [4]. The rate of blood gas sampling therefore tends to be compromised, which results in a poor diagnostic yield. The pain associated with 'skin breaks' has further adverse implications. In the short term, pain causes fluctuations in heart rate and blood pressure, with a resulting decrease in the amount of oxygen circulating in the blood [5]. The associated release of stress hormones results in slower metabolic thalamic growth, with reduced white matter and subcortical brain matter maturation [6]. This results in poorer cognitive, neuromotor and later life behavioural outcomes [7]. Preterm neonates are particularly sensitive to pain and its longer term effects [8].

Monitoring CO_2 in the tidal gas provides an alternative non-invasive indicator for ventilation effectiveness, airway integrity and metabolic activity.

When an end-tidal plateau in the exhaled CO_2 is obtainable, then the end-tidal CO_2 ($EtCO_2$) measure can correlate to the alveolar $PaCO_2$. A reliable $EtCO_2$ measure can therefore enable a significant reduction in the requirement for invasive blood gas sampling [9]. The shape of the volumetric CO_2 curve (capnogram) can further inform of changes to physiologic deadspace and indicate certain lung conditions or injury [10]. However, tidal gas CO_2 monitoring in neonates has historically been limited by its physiological and technical challenges, including from gas mixing and excessive deadspace in the devices [10].

SIDESTREAM VS MAINSTREAM

Sidestream capnography diverts a small sample of the respiratory gas, via a port tapping into the breathing circuit very near to the patient's airway. The sampling gas flow rate is continuous and, normally, in the range 50ml/min to 150ml/min. The gas sample travels through a thin tube to an infrared spectrographic analyser that is approximately 1.5m distance away from the patient. The gas travel time creates a small latency in producing the measurement data.

In mainstream capnography, the infrared spectrographic analyser is deployed directly across the respiratory gas stream, near to the patient airway. This has two principal advantages. Firstly, it is passive, in that it does not divert any of the respiratory gas. Secondly, it reduces the measurement latency to near real-time.

The advantage of 'real-time' CO_2 measurement data is somewhat academic. The important $EtCO_2$ measure is updated breath by breath, and a small latency is of no clinical consequence. In practice, signal filtering, electronic processing and inter-modules data transfer does also cause latency in the mainstream device's 'real-time' data – although much smaller.

A reliable $EtCO_2$ measure can enable a significant reduction in the requirement for invasive blood gas sampling.

Similarly, the measurement systems for airway pressure and flow-volume also have small and varied latencies. Therefore, 'real-time' data from the multiple monitoring systems can rarely be combined, into producing meaningful new information, without further prior post-processing or delaying or otherwise aligning the data streams.

The sidestream technology has a number of advantages over the mainstream. Firstly, its lower deadspace airway adapter, when used in combination with the additional space of a flow sensor, makes it significantly more viable for the very smallest patients. Secondly, a sidestream adapter places less bulk and weight in the patient airway interface, making it easier to reposition the patient and being potentially more comfortable. Thirdly, sidestream technology has greater flexibility in application with a wider variety of invasive and non-invasive patient interface types. Fourthly, it is generally an easier-to-manage asset. For example, the 'fixed' installation sidestream analyser is comparably less prone to become damaged or go missing, than the 'floating' mainstream analyser is.

The dilution effect that gas turbulence/mixing has on the $EtCO_2$ measurement in neonatal ventilation has historically presented a challenge in both technologies. Water moisture in the respiratory gas also presents a challenge in both technologies. Water droplets can deposit on the mainstream device adapter's optical sensing window; and water droplets can enter the sidestream sampling tube.

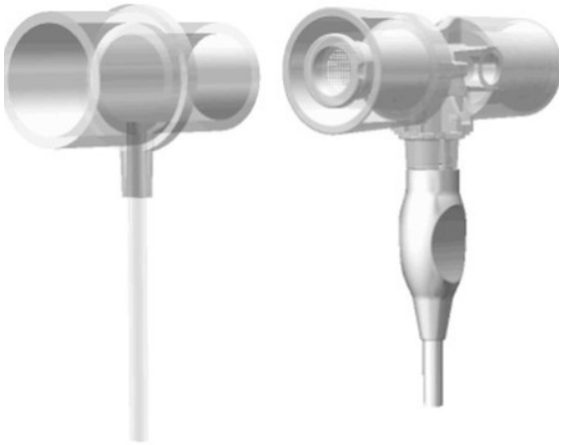

Figure 1: Prior art configuration of a bi-directional hot wire flow sensor and a separate sidestream adapter for CO_2 monitoring.

The configuration illustrated in figure 1, with a sidestream adapter inserted in between the flow sensor and the endotracheal tube, has historic use in neonatal respiratory care. The sidestream adapter often has a bore-reducing core for reducing its deadspace (not shown here).

DEADSPACE

Deadspace is the space in which oxygen (O_2) and carbon dioxide (CO_2) gases do not participate in gas exchange. Deadspace causes some O_2 depleted and CO_2 enriched gas to remain in the airway for rebreathing and therefore reduces the effective perfusion. The concept distinguishes between anatomical deadspace (tracheal, bronchial and alveolar spaces) and technical deadspace (airway tubes and adapters). Neonatal clinicians want to minimise all deadspace, but they also need accurate information on pressure, flow-volume rates and CO_2 elimination.

$PaCO_2$ increases exponentially with deadspace. A larger deadspace demands undesirably larger tidal volumes [11]. Just 0.2ml added deadspace can make a significant difference in preterm neonates [12].

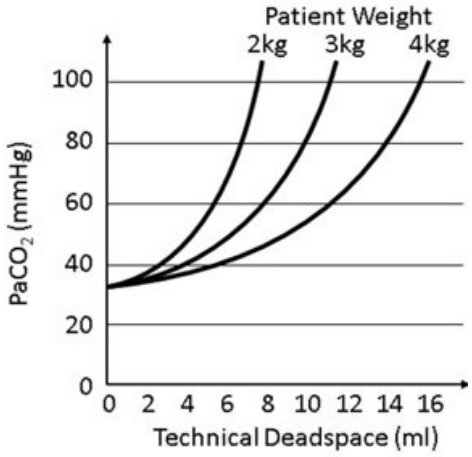

Figure 2: Pa CO_2 vs Technical Deadspace. Reproduced from Pearsall et al [11].

The tube bore cross-section therefore has an optimum dimension which relates to the ventilation pressures and target volume, which in turn relate to the size of the patient. In consideration of the smallest patient group, the total technical deadspace should ideally be less than 1ml. This deadspace volume should not be considered merely as a limit for enabling ventilation of the very smallest preterm neonates All infant ventilation, including of a 4.5kg normal term neonate, in fact becomes more efficient with a smaller deadspace.

Common prior art CO_2 adapters for neonatal care are in fact adult adapters, redesigned with a bore-reducing core. Similarly, neonatal flow sensors also have a bore-reducing core, as illustrated in figure 1. This solution is fine when the devices are used in isolation of each other; but the two cores can interfere and prevent assembly of the devices for combined flow and CO_2 monitoring. One of the two devices therefore has to omit the bore-reducing core in the devices interface. Prior art solutions, as indicated in figure 1, typically have a combined deadspace between 2ml and 5ml.

Figure 3 illustrates how gas flow turbulences prior to reaching the sidestream sampling port causes the end-tidal gas unit becoming mixed with other tidal gas. This causes a dilution of end-tidal gas and an under-diagnosis of the true EtCO_2 value. This error can be considerable for infant patients, where the end-tidal gas unit is very small in volume and particularly short in time.

In addition to the deadspace resulting in an under-measurement of the $EtCO_2$, as an indicator for $PaCO_2$, the same deadspace may in fact result in and mask an actual increase in $PaCO_2$, by detracting from the amount of fresh gas exchange and by causing rebreathing of previously exhaled gas. So called 'low deadspace' adapters still add a significant amount of space and gas mixing, where the smallest patients are concerned.

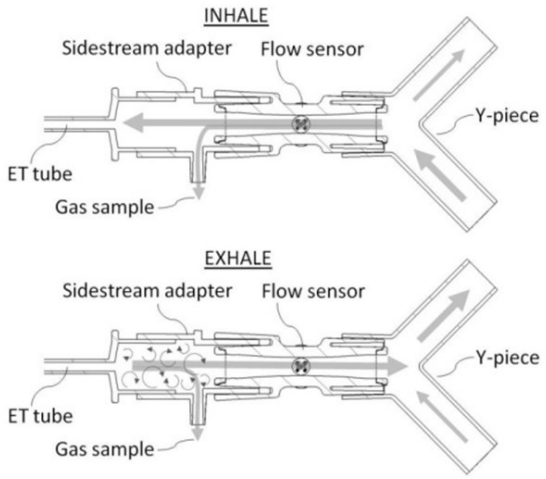

Figure 3: Respiratory gas and sampling gas flows in a prior art configuration of a hot wire flow sensor and a separate sidestream adapter.

SIDESTREAM GAS DIVERSION

Figure 3 illustrates that when a sample gas is diverted from the inhaled gas flow, then a tidal flow over-measurement error occurs because the diversion happens after the total gas has crossed the flow sensing element. The error is compounded on exhalation, when a tidal flow under-measurement occurs because the sample is diverted from the actual exhaled gas before its flow-volume is measured. The discrepancy between inhaled and exhaled tidal volumes manifests as inaccuracy in the tidal volume measure and it creates a false leak measurement. With the tidal volume in infants being 4 to 8ml/kg weight, the smallest viable patients, weighing down to 300gr, may tolerate as little 2ml tidal volume.

The solution to the excessive deadspace and potential measurement errors resulting from a sample gas diversion, is found in combining the two monitoring functions into a single purpose-designed device.

Modern ventilators tend to reduce this complexity, by compensating the tidal flow measurements for the continuous 50 ml/min sidestream. This means the ventilator algorithm will estimate for up to 50% of unmeasured flow. Any secretion and sampling line obstruction, or sidestream pump wear, has potential for quickly creating a significant estimation error. Such an error in the measurement system affects the calculations of lung compliance and airway resistance values, potentially providing clinicians with flawed decision information.

COMBINATION DEVICE

The solution to the excessive deadspace and potential measurement errors resulting from a sample gas diversion, is found in combining the two monitoring functions into a single purpose-designed device.

Figure 4: Purpose-designed combination flow sensor with gas sampling port .

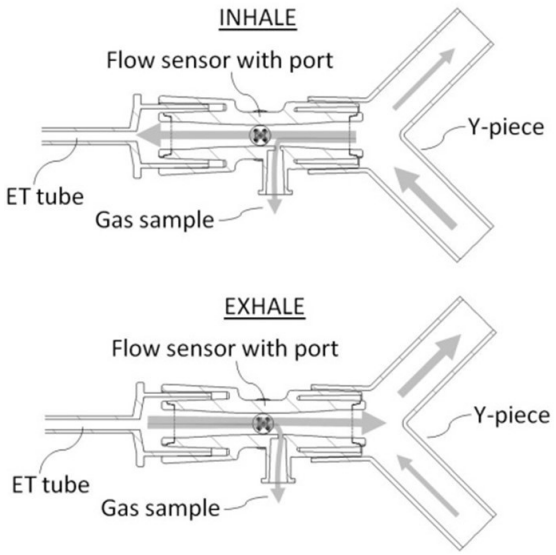

Figure 5: Respiratory gas and sampling gas flows in a purpose-designed combination flow sensor with gas sidestream port.

In the purpose-designed combination device, the sampling gas is diverted from the inhaled gas flow prior to reaching the flow sensing element. And, sampling gas is diverted from the exhaled gas flow after having crossed the flow sensing element. It is found that maintaining a certain, quantified upstream separation distance between the flow sensing element and the gas sampling port eliminates any interference over the therapeutic tidal flow ranges. An excessive separation distance would require the flow sensor be increased in length, with a resulting penalty from added deadspace and more turbulence mixing in the respiratory gas would occur prior to collecting the sampling gas. An optimum separation distance has therefore been identified, which eliminates measurement errors in both inhaled and exhaled tidal volumes for the common sidestream gas flow rates between 50ml/min and 150ml/min.

The combination device has the same 0.8ml deadspace as a conventional flow sensor, without adding any space from a separate sidestream adapter.

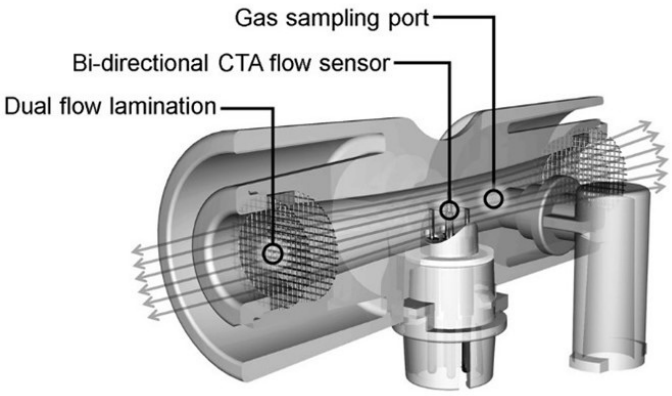

Figure 6: Arrangement of combination measurement devices.

The combination device has the same 0.8ml deadspace as a conventional flow sensor, without adding any deadspace from a separate sidestream adapter. By eliminating the step contractions and expansions in the flow path, from the otherwise overlapping adapter connector, the combination device has improved fluid mechanical efficiency and less turbulence mixing. The reduction in the multiplicity of adapter parts also reduces the risks of a mismatch between different manufacturing dimensional tolerances, which are inherent risks of incompatibility and sources of actual gas leaks. It further eliminates the unmitigated misconnection risk – i.e. the user being able to accidentally place the sidestream adapter between the Y-piece and the flow sensor, which would potentially result in significant errors in both flow-volume and $EtCO_2$ measurements.

DEVICE PERFORMANCE

The test system uses a 1,500ml/min reciprocal diaphragm pump for drawing the sampling gas. The sampling gas flow rate is varied using a tube clamp and is verified with a calibrated flow analyser.

The elastic 'bounce' in the silicon test lung introduces an inherent noise in the test system, exceeding that of a natural lung.

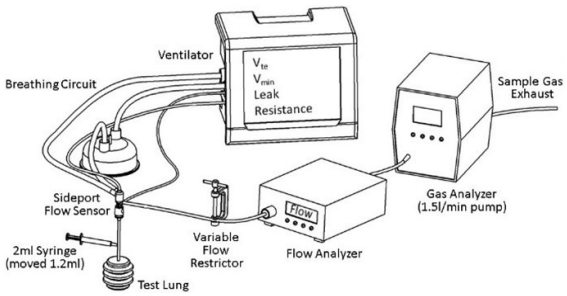

Figure 7: Combined flow sensor testing system.

TIDAL VOLUME DEVIANCE TEST:

Performed in CMV mode Vte 8ml, Vmin 320ml, and in HFOV Vte 10ml, Vmin 6,200ml. Minute volume is observed under conditions of varying the sampling gas flow rate between 0 and 1,500ml/min.

FALSE LEAK TEST:

Performed in CMV mode at Vte 4ml and Vte 15ml. Measured leak is observed under varying Vte and sampling gas flow rates. Follow-up comparison measurements performed using a commercially available and well-known brand of neonatal sidestream CO_2 analyser and adapter.

MISSED BREATH TEST:

Performed in flow-triggered PSV mode. Manually controlled 1.2ml syringe pulls. Flow trigger sensitively is set excessively low, so that 20% of syringe pulls under zero sidestream condition fails to trigger a breath. Change in missed breath rate is observed under increasing sampling gas flow rate.

FALSE BREATH TEST:

Performed in flow-triggered PSV mode. Silicon test lung is placed on a vibrating surface (noisy compressor enclosure).

Testing results show the flow sensor maintains acceptable performance with gas sampling flow rates up to 150ml/min.

Flow trigger sensitivity is set excessively high, so that the vibration noise results in 10 false triggers per minute under zero sidestream condition. Change in false breaths observed under increasing sampling gas flow rate.

WAVEFORM VISUAL QUALITY:

Wave 'noise' observed and recorded for subjective evaluation.

RESULTS AND QUALIFICATION:

Table 2: Test results and qualification against current state-of-art in neonatal care.

Sidestream flow rate (ml/min)	Tidal volume deviance	Rouge leak	Missed breath*	False breath*	Waveform visual quality	Performance qualification
0	0.0%	0.0%	0.0%	0.0%	Acceptable	Acceptable
50	0.0%	0.0%	0.0%	0.0%	Acceptable	Acceptable
150	0.1%	0.3%	0.0%	4.0%	Acceptable	Acceptable
500	0.8%	6.0%	0.0%	30%	Acceptable	Tolerable
1500	2.8%	18.0%	0.0%	105%	Unacceptable	Intolerable

* measures represent the percentage worsening in function.

Repeating the tidal volume deviance and false leak test at 50ml/min, using a conventional flow sensor in combination with a well-known brand of neonatal sidestream CO_2 analyser and separate adapter, results at 4ml Vte in 7% tidal volume measurement deviance and a 12% false leak.

ANALYSIS

The testing results show the flow sensor maintains acceptable performance with gas sampling flow rates up to 150ml/min. Beyond this sampling flow rate, both the tidal volume measurement error and false leak may become unacceptable. It should be noted that testing was performed using a worst-case reciprocal vacuum pump, recognised for causing a pressure pulse noise at the sampling port.

At 1,500ml/min, the reciprocal pump strokes become obviously visible on and detract from the visual quality of the ventilator waveform display.

The sampling gas flow rate does not affect the ventilator ability to correctly detect the onset of breath, in performing low latency, flow triggered synchronisation.

The greyed cells in table 2 indicate the unacceptable performance results. For the 'false breath' indicator, it should be noted that the measure was obtained from a system already forced into instability, where it produced 10 false triggers per minute. In practical application, the sensor is not subjected to such worst-case condition, as during this test. Hence, 500ml/min sidestream flow rate can be deemed borderline tolerable for needed clinical applications.

Follow-up testing of a conventional flow sensor in configuration with a commercially available neonatal sidestream CO_2 monitor shows that the prior art separate airway adapter results in significant measurement errors; whereas using the purpose-designed combination device does not result in any measurement errors. Furthermore, the prior art flow sensor and separate sidestream adapter has a combined deadspace of 2ml or more, whereas the purpose-designed combination device has a deadspace of just 0.8ml.

CONCLUSION

The purpose-designed combination flow sensor with gas sampling port offers improvements over prior art gas sampling adapters. The combination device assures measurement systems integrity when used with sidestream CO_2 analysers that have sampling gas flow rates up to 150 ml/min.

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