COMBINATION FLOW SENSOR WITH CO_2 SAMPLING PORT

ABSTRACT

Technical aspects of combining tidal flow-volume and carbon dioxide monitoring in the smallest neonatal patients are introduced. The sources of deadspace and of flow-volume measurement inaccuracy are described. The features and benefits of a neonatal combination flow sensor with integrated respiratory gas sampling port are highlighted, and its performance characteristics are demonstrated. A prior art standard flow sensor connected with a standard gas sampling adapter has a combined deadspace of 2ml, or more, and produces 7% tidal volume inaccuracy and 12% rogue leak measure, when ventilating a 4ml tidal volume. By comparison, the combination flow sensor with an integrated gas sampling port has a deadspace of 0.8ml, and it produces accurate tidal volume and leak measures. 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.

INTRODUCTION

Developments in respiratory care equipment focus largely on adult care requirements, and requirements in the relatively smaller area of neonatal care tend to become appended as a technology scaling activity. However, certain performance characteristics translate poorly from the adult to the neonatal operating range. This has led to divergence in the state-of-art in two key monitoring technologies in adult and neonatal care.

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, where input parameters are adjusted according to the physiological response they produce. There is no hard and fast rule for prescribing a tidal volume in neonates. There is, however, good evidence that synchronised ventilation, 'gently' providing the minimal necessary tidal volume, can help protect against chronic lung disease (CLD). A variety of literature recommends between 4 and 8 ml/kg patient weight. This amount can vary dynamically as the patient lung condition changes during a care session. Monitoring of the proximal flow and volume cycle, in relation the associated airway pressure cycle, can help indicate the lung condition. In order to obtain effective flow triggered ventilator synchronisation, with the onset of patient breath, the sensor should be capable of measuring flows as low as 0.2 l/min. Such sensitivity, with accuracy, is unattainable using the pressure differential sensor technology that prevails in adult care.

Arterial carbon dioxide concentration ($PaCO_2$) reflects cardiac output and pulmonary blood flow. Because carbon dioxide (CO_2) in the supplied ventilation gas is practically zero, the partial pressure of CO_2 in the patient alveoli (PCO_2) closely represents that in the patient blood flow. Exhaled gas originating from the alveoli is generally the last to be washed-out, in the end-tidal volume. Other tidal gas inhaled into and out from the upper airway and the lung branches does not reach the alveoli and does therefore not contain CO_2 that is exchanged in the current breath (it does contain CO_2 that is residual from previous breath cycles). End-tidal CO_2 ($EtCO_2$) monitoring provides a valuable indicator whether optimal ventilation is achieved.

SIDESTREAM VS MAINSTREAM

Sidestream capnography diverts a small sample of 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, 50ml/min to 150ml/min. The gas sample travels through a thin tube to an analyser device that is approximately 1.5m distance away from the patient. The travel time creates a small latency in producing the measurement data.

In mainstream capnography, the sensing element of the gas 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 produces 'real-time' data.

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 cause latency in the mainstream device 'real-time' data also – although much smaller. Similarly, the measurement systems for airway pressure and flow 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 of one or more of the data streams.

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

Water moisture in the respiratory gas presents a challenge in both technologies. Water droplets can enter the sidestream sampling tube; and water droplets can deposit on the mainstream device adapter's optical sensing window.

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

Figure 1 illustrates the current most commonly used combination system in prior art neonatal care, where a separate sidestream adapter is inserted between the flow sensor and the patient endotracheal tube.

DEADSPACE

Deadspace, in our technical context, is the combined volume that exists within the proximal flow sensor, the airway adaptor and tube connectors. Deadspace buffers exhaled gas from reaching the breathing circuit exhaust channel. The patient subsequently rebreathes proportional amounts of $EtCO_2$ rich gas.

One way to minimize deadspace is to 'throttle down' the tubular bore through the flow sensor and the airway adapter. However, this has effect of simultaneously increasing the gas flow resistance and the effective emptying of the lung. The tube bore cross-section therefore has an optimum dimension which relates to the ventilation flow rate and volume, which in turn relates to the size of patient. In consideration of the smallest patient group, the total combined deadspace should ideally be less than 1ml.

Typical prior art CO_2 airways 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. This solution is fine in isolation; but the two cores interfere, and prevent assembly for combined flow and CO_2 monitoring. One of the two parts therefore

has to omit the core feature. Prior art solutions, as shown in figure 1, have a combined deadspace between 2ml and 5ml.

Figure 2 illustrates how gas flow turbulences prior to reaching the sidestream sampling port causes the end-tidal gas unit becoming mixed with other tidal gas. The effect is an under-diagnosis of the actual $EtCO_2$ value. This effect can be considerable for pre-mature and 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 indicator for $PaCO_2$, the same deadspace may in fact result in an actual increase in $PaCO_2$, by detracting from the amount of fresh gas exchange and by causing rebreathing of previously exhaled gas.

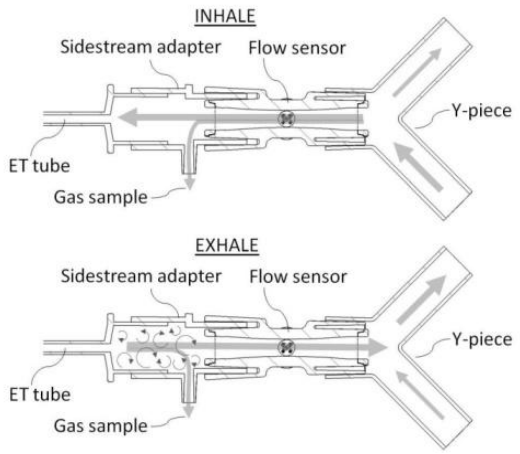

Figure 2 Respiratory gas and sampling gas flows in a prior art configuration of a hot wire flow sensor and a separate sidestream adapter

SAMPLING GAS DIVERSION

Figure 2 illustrates how when a sample gas portion is diverted from the inhaled gas flow, a tidal flow over-measurement error occurs because the gas sample is diverted after having already 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 volume manifests as inaccuracy in the tidal volume measure and it creates a rogue (phantom) leak measurement. With the tidal volume in infants being 4-8ml/kg weight, the smallest viable patients, weighing down to 300gr, may tolerate as little 2ml tidal volume. At 50 breath-per-minute, this equates to a minute volume of approximately 100ml/min. In a severe case, as in the prior art described in figures 1 and 2, the diversion of sampling gas can result in a theoretical 50% under-measurement of the actual tidal flow-volume. Modern ventilators would register such loss as a leak at the patient interface. Ventilation is an output driven therapy, where the target tidal volume is, typically, adjusted according to patient response, and on-going ventilator adjustments can generally take into account and compensates for a certain amount of leak. However, the leak effect is a further level of complexity for the clinician to consider, and thereby introduces a risk of sub-optimal ventilator settings. Accidental over-distension of the lung may cause irreparable tissue damage. Often the patient metabolic rate is calculated from gas volume and carbon dioxide and oxygen concentration variables. Such calculations are potentially unreliable when using leak compensated volume estimation. It is therefore desirable to eliminate tidal volume measurement errors and rogue (phantom) leak measurements.

COMBINATION DEVICE

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

Figure 3 Purpose-designed combination flow sensor with gas sampling port

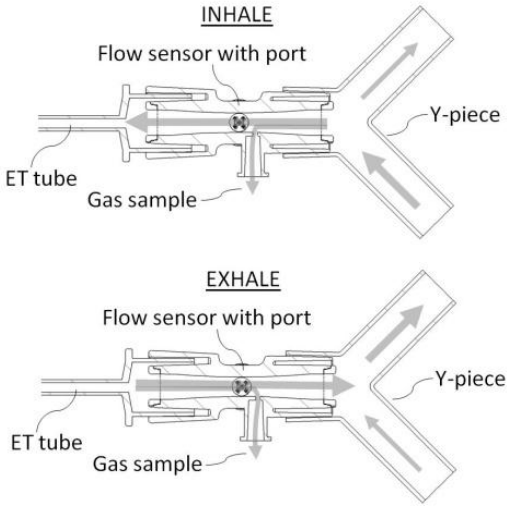

Figure 4 Respiratory gas and sampling gas flows in a purpose-designed combination flow sensor with gas sampling port

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 flow sensing element and the gas sampling port eliminates any adverse measurement effect, over the therapeutic tidal flow ranges and for typical sampling gas flow rates. An excessive separation distance would require the flow sensor be increased in length, with a resulting penalty from added deadspace. Also, more turbulence mixing in the respiratory gas would occur prior to diversion of sampling gas. An optimum separation distance has therefore been identified, which eliminates measurement errors in both inhaled and exhaled tidal volumes for the common sampling gas flow rates between 50ml/min and 150ml/min.

The combination device illustrated in figure 3 has the same 0.8ml deadspace as a standard flow sensor, without any additional deadspace from a separate adapter port. By eliminating the step contractions and expansions in the flow path, from otherwise overlapping connectors, the combination device has improved fluid mechanical efficiency and less turbulence mixing. Reduction in the multiplicity of adapter parts also reduces the risks of mismatch between different manufacturing dimensional tolerances, which are inherent risks of incompatibility and sources of actual gas leaks.

PERFORMANCE TESTING

The testing system uses a 1500ml/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, which exceeds (i.e. is worse case than) that expected in a natural lung.

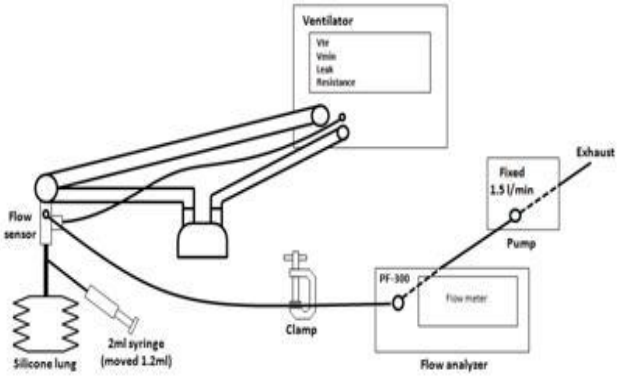

Figure 5 Combined flow sensor testing system

TIDAL VOLUME DEVIANCE TEST:

Performed in CMV mode at Vt 8ml, Vmin 320ml, and in HFOV at Vt 10ml, Vmin 6.2 L. Vmin is recorded under conditions of varying the sampling gas flow rate between 0 and 1500ml/min.

ROGUE (PHANTOM) LEAK TEST:

Performed in CMV mode at Vt 4ml and Vt 15ml. Ventilator measured leak percentage value is recorded under the two different Vt and varying 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 PSV mode. Mechanically controlled 1.2ml syringe pulls. Flow trigger sensitively set high, so that 20% of syringe pulls under zero sidestream condition fails to trigger a breath – i.e. reference level missed breath rate is 20%. Change

in missed breath rate is recorded under increasing sampling gas flow rate.

FALSE BREATH TEST:

Performed in PSV mode. Silicon test lung is placed on a continuously vibrating surface. Flow trigger sensitivity is adjusted, so that the induced vibration noise results in 10 false triggers per minute under zero sidestream condition. Conditions are worse than in any real clinical application. Change in missed breath rate is recorded 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 rogue leak test at 50ml/min, using a standard flow sensor in combination with a well-known brand of neonatal sidestream CO_2 analyser and separate adapter, results at 4ml Vt in 7% tidal volume measurement deviance and 12% rogue (phantom) leak.

ANALYSIS

The testing results shows 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 rogue (phantom) 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 1500ml/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 has no effect on the ventilator ability to correctly detect the onset of breath, for synchronisation purposes.

The greyed cells in table 2 indicate some unacceptable performance values. For the 'false breath' indicator, it should be noted the measure was obtained from a system already forced into borderline instability – by the test lung being placed on a vibrating surface. In practical clinical application, the sensor is not subjected to such worst-case condition. Therefore, the 500ml/min sidestream flow rate is deemed borderline tolerable for needed clinical applications – i.e. where the device clinical benefits may outweigh the reduced technical ability to discriminate noise from an actual breath.

Follow-up testing of a standard flow sensor in configuration with a commercially available neonatal sidestream CO_2 monitor shows 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 standard flow sensor and separate standard 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 neonatal combination flow sensor with gas sampling port offers improvement 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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