Sidestream Sampling Flowsensor from Europlaz – Project Log

Communications From Europlaz (in reverse chronological order)

From: Frede Jensen
To: Steve Nixon
Date: 26 Mar 13

Dear Steve

I have been unsuccessful in trying to contact you, and am uncertain if/how Viamed wish to proceed with the CO2 analyser?

In the interest of getting quantities of our own products moving, Europlaz now need to refocus on parallel initiatives with other potential distributors.

Kind regards

Frede

From: Frede Jensen

To: Steve Nixon
Date: 13 Mar 13

Dear Steve

I am trying to understand where we are regarding the capnometry products. Any updates?

Kind regards

Frede

From: Frede Jensen
To: Steve Nixon
Date: 4 March 13

Dear Steve

Would it be time to meet-up and progress the details of pricing, packing units, regulatory, labelling etc?

Kind regards

Frede

From: Frede Jensen
To: Steve Nixon
Date: 13 Feb 13

Dear Steve

Showed the analyser at SLE today. They have increasing requests for such a device to combine with their ventilators, and are positive about a need for one in their own products catalogue. On occasion, they have re-sold third party (Oridion) sidestream analysers, for satisfying particular tender requirements.

Two questions that I was unable to clearly answer:
1) User manual states a figure for EtCO2 accuracy. Is this performance assured right down to the very smallest tidal volume of just 2ml?

2) How does the pulseoximeter compare to Massimo, in neonates? I owed up to having no real experience of the device, and stated my understanding that the device doesn't match the Massimo performance, but that Viamed are working on a further improvement.

Overall, the meeting was very positive about the Viamed device. SLE like it. It ended with a suggestion that SLE and Viamed get in contact.

We never got to talk about CO2 monitoring in HFOV. It didn't seem to be forefront in the minds at SLE.

SLE remain somewhat concerned about Europlaz offering the sideport flow sensor to potentially competition sales channels. This concern relates less to Viamed, but more to Europlaz supplying to other ventilator manufacturers. At the same time it was acknowledge that we need to get numbers up, to make better use of established production capacity. SLE's concern is resolvable from Europlaz. We will be staying clear of any of the major conflicts (seem to be mainly Acutronic).

We will return the demo unit to Viamed in the next days.

Kind regards

Frede

From: Frede Jensen
To: Steve Hardaker
Date: 29 Jan 13

Dear Steve

If SLE, Acutronic and GE have around 70% of the UK neonatal ventilation market, Draeger has most of the remaining 30%. Stephan has one, maybe two, sites. MAQUET and CareFusion may a few token machines in use. That is counting ventilators only. I am discounting old machines kept as backup in hospiyal stores. If we include CPAP, then CareFusion counts more.

Draeger is likely the most reputable brand name, but it is also priced thereafter. Until launch of their new VN500, in the last year, their old Babylog8000 was getting very dates. Draeder have best-in-class literature and user support programmes. However, the SLE5000 is a better specification and value-for-money neonatal ventilator. On a global level, the order of neonatal market share is probably SLE, Draeger, MAQUET, CareFusion, Corvidien, GE, Acutronic, Stephan, Heinen & Loewenstein etc. Saying this, my view is bound to be somewhat SLE-biased, and is 3 years out of date.

Our flow sensor is not compatible with Draeger. It has occurred to us making a copy, including with the patented sideport solution. As you know, Draeger are good at creating lock-outs for competing consumables. In an ideal situation, Draeger would ask us to produce their flow sensor; but we don't expect this to happen.

Kind regards

Frede

From: Frede Jensen
To: Steve Hardaker
Date: 28 Jan 13

Dear Steve

"10,000" referred to SLE global install-base, and was meant to illustrate the demand for your CO2 analyser. SLE is market leader, with about a quarter of the global market. Global sales of neonatal ventilators are difficult to pin down at the moment. In 2006, the industry quoted 5,000 ventilators per annum. Since then, growth has become strong in India, China, Russia; but world economics may have detracted. I guess the number is 6 - 7,000 new neonatal ventilators by now. Each ventilator could potentially do with a combination CO2 analyser; but the actual penetration is currently poor. Until now, no-one have cracked the combination measurement problems (deadspace and flow errors). Future new ventilators will integrate CO2 monitoring. The trend has started already. However, there is a huge aftermarket in the about 40,000 pre-existing neonatal ventilators, which all potentially need a device like Viamed's - providing it can overcome the flow sensing combination issue.

In terms of neonatal ventilators: UK and EU market is stagnant. Global market is growing at 8-15% p.a. Growth in single-use consumables is >15% p.a. For example, UK has 1 ventilator per 15 babies in need of respiratory care annually. In India the figure (from 2005 data) is 1 ventilator per 3,200 babies. You can see how India, China, Russia, South America have enormous grown potential.

UK NHS NICUs/SCBUs treat 19,500 babies p.a. (DoH 2007), with about 1,300 ventilators; or an average of about 5 per care unit. According to DoH, the number of care units has reduced to 260 by 2010, with the formation of 50-odd 'centres of excellence' (where the bulk of the most advanced equipment is situated).

On average, each ventilator consumes 40 sets of breathing circuits p.a. Guestimating that our flow sensor is compatible with about 70% of neonatal ventilators in the UK market (SLE home, and a good number of Acutronic and GE machines), the UK demand is about 35,000 'sensor sessions'. Considering an element of reuse, total annual sales are about 20,000 (non-sideport) sensors in the UK. There is a continual shift away from reuse, and more babies are now being born, so this number is growing – even though the ventilator market is stagnant. Sales are currently being met by SLE, Inspiration Healthcare and GE - in that order of market share.

Sales will convert from 'non-sideport' to 'sideport' type flow sensors, at the rate of uptake in sidestream CO2. CO2 monitoring is an important clinical tool in ventilation care. My own feeling is that, once it can be demonstrated to work in combination with flow monitoring, it will soon become recognised as an essential clinical requirement. There is good potential for neonatal sidestream CO2 taking off, now that it can be effectively combined with flow sensing.

Kind regards

Frede

From: Frede Jensen
To: Steve Nixon
Date: 23 Jan 13

Dear Steve

Unfortunately, SLE have now had to reschedule our meeting on 25th.

I have mentioned to Bernard Nelligan (managing director) that Viamed will be at Arab Health, and may find time to demonstrate the device. Martin Pearcy (sales director) will be the other person to see. Martin understands CO2 monitoring well. SLE actively promotes 'open lung' ventilation (see training seminars on SLE website), which relies on monitoring of the EtCO2 value/trend (not the real-time curve). Inspired CO2 may be of interest as an indicator for rebreathing in conventional ventilation. The SpO2 could wow them, as an additional benefit thrown in.

Headline points of interest to SLE:
- Neonatal specific defaults mode.
- Easy to operate. Simplicity.
- Combines essential tools of capnography and pulseoximitry into a ventilator combination device. Could offer SLE a ready-made solution, including own-labelling, for the aftermarket of existing ventilators install-base – and for new sales.
- Medirail or pole clamp option.
- Multiple languages ready.
- Combines with sideport flow sensor, to make the only available option for preterm and low birth weight patients down to 300g. No other CO2 solution from any manufacturer is viable for patient below 1.5kg (or more). The SLE ventilator treats patients down to 300g, so why should the capno feature be any different.
- Neonatal SpO2 sensor single-use and reusable option.
- Fast start-up.
- Improved moisture handling.
- Nitric dioxide compensation. SLE markets a NO delivery system for its ventilators. NO converts to N2O, when combining with moisture in the lung and breathing circuit. SLE device monitors N2O concentration, and they will know the typical levels concerned. I don't think they know that N2O can mimic CO2 in capnography.
- USB data interface – e.g. could send parameter values to ventilator.
- Opportunity to take a market lead in developing a protocol and CO2 indicator for use in HFOV; together with a clinical partner.

I would simply have left the device in its first screen mode, and then just talked through all of the other functions that the device has (not showing them every sub-menu). Only once they have become 'comfortable' with the first screen, would I have shown the large digits and trend screens. Anything that looks complicated and requires a lot of button-presses for users to learn/remember will be off-putting to them – it generates a user support need. They can always learn about the sub-menus, once they have decided they like/want the device. Make sure to switch off the pulse beeps (Martin hates alarm sounds, because clinicians do).

Obstacles that SLE may present:
- Preference for real time capnogram – i.e. mainstream (they happen to make use of Novametrix mainstream NICO at SLE training seminars). 1) Mainstream has too much deadspace and bulk, to ever be used with the smallest patients. The mainstream airway adapter isn't compatible with their flow sensor (both have a cored centre. Same for Philips device). 2) Unlike in adult care, the real time curve provides little-to-no information for neonates. Neonates have a high rate of short breaths, and the EtCO2 plateau is only about 10-20mS. You simply can't determine any information from the wave curve. 3) Sidestream requires less user skills to connect and maintain, and device is less exposed to accidental damage. SLE would want to market the hassle-free product.

- SLE may be considering future integration into a ventilator, and have possibly already been

talking to Philips or Oridion. 1) Other similar devices do not combine CO2 and SpO2. 2) Current Viamed device is ideal for retrofitting to existing ventilators install base (aftermarket). 3) Viamed device will provide SLE with learning about the marketing and use of capnography and pulseoximitry, and thereby help them specify future ventilator integrated requirements – which Viamed may also be able to help them with.

The flow sensor product page on the Europlaz website has a white paper explaining the benefits and technical aspects of the sideport sensor.

I am out of the office tomorrow, but contactable on 07935 312 176, if you wish to discuss.

Good luck with the show.

Kind regards

Frede Jensen

From: Frede Jensen
To: Steve Hardaker
Date: 21 Jan 13

Dear Steve

For information, we have had a quote back from our sterilisation contractor, for 6-8 weeks to perform the necessary batch dose and bioburden study. The time delay may fit fine with the other details that would need completing – e.g. CE-marking, documentation and labelling. But it is somewhat long, for simply labelling a smaller quantity for pre-market evaluation.

In the mean-time, we are sending you another 10 sensors FOC, as medically clean (non-sterile) samples. The Europlaz label can be pealed off, without causing bag damage. Viamed can then re-label as appropriate for its investigation and traceability purposes.

The Europlaz conformity assessment is complete, for CE-marking and release into clinical use. The performance validation is performed using a worst-case pump technology, and confirmed on a representative CO2 analyser (Respironics LoFlo). The validation is applicable to any model analyser with a sampling rate up to 150ml/min – which includes VM-2500-S. The new flow sensor basically combines two clinically proven technologies, which already have established combination use. The clinical evaluation is based on the pre-existing clinical data, from literature relating to flow sensing and to CO2 monitoring. In accordance with EU guidance (MEDDEV. 2.7.1.), with regards to sufficiency of pre-existing clinical data, it has not been necessary to perform additional patient trails.

Thank you for the heads up regarding HFOV. The explanation makes sense and should be acceptable to SLE for now. I am not aware of any clinical protocol, yet, for monitoring CO2 in HFOV. It is a new area that will need investigating. I will indicate to SLE that Viamed is capable of further developing the software, subject to what requirements become defined at a future date. HFOV is also starting to gain use in adult care (CareFusion in the US. Inspiration Healthcare have a device on trail in Oxford). My guess is that someone will eventually evolve a HFOV-CO2 monitoring protocol. So why not get your name associated with it.

I expect that meeting with SLE and others at Arab Health, will provide Viamed with a better picture of the product potential. Assuming that key people will be away from the office during next week, can I suggest that we meet up again after Arab Health, and involve our regulatory and commercial people on the details? Although, if preferred, we can also make a meeting earlier.

Kind regards

Frede

From: Frede Jensen
To: Steve Hardaker
Date: 18 Jan 13

I am not in the office tomorrow, so here is just a quick response to the points raised. I will try get in contact with the office, to be able to get more details. If not I will come back to you Monday.

The sensor is CE-marked by Europlaz, as a Class I generic combination device. Viamed may reference to the Europlaz technical file, in establishing its own CE-mark. It may be easiest if the regulatory representatives at Viamed and Europlaz meet-up to get the necessary details in place.

The samples are clinically clean, which tends to be the norm for breathing tubes. The fact that sensors are non-sterile does not preclude their use. One client has preferred the 'sterile' option for the single-use sensor, for reasons that the pre-existing ventilator user manual only refers to the reusable sensor, and therefore, confusingly, stipulated flow sensor sterilisation between patient uses. Another client has in fact specified the non-sterile option. I guess there is higher perceived customer-value in 'sterile'.

It is possible to prepare sterile samples for you, but I need to confirm the timing for this – i.e. when we can have a batch going to our sterilisation contractor and when the process validation can be completed. Where a Class I device is 'sterile', the conformity assessment of the sterilisation process has to follow that of a higher class device. This has been done for the SLE process, for the SLE label and CE-mark, but will need to be revalidated when we ship to a differently named distributor. That is unfortunately how the regulatory body sees it. On a positive note, we have to date already shipped 70,000 sterile flow sensors (non-sideport) and the operation well proven.

We can redesign the label to your specification. I would suggest that our regulatory representatives can agree the details when they meet.

The flow sensor is intended and validated for use in HFOV – also with the CO2 analyser collecting a sidestream. Obtaining a meaningful CO2 analysis in HFOV, however, may be more difficult. My guess is that the small tidal volume and gas mixing is likely to cause the capnogram being more of a flatline, representing the 'mean CO2' level over the very fast breath cycle. However-however, this 'mean CO2' value could prove a very important indicator for HFO ventilation efficiency – i.e. indicate the amount of CO2 elimination that is achieved. It is new thinking and clinical research remains to be being done. There will be university hospitals in the UK, or elsewhere, interested in such research; and there is good international kudos to the manufacturer whose equipment helps evolve the solution. Maybe something Viamed and SLE could collaborate on with a clinical partner?

Kind regards

Frede

From: Frede Jensen
To: Steve Hardaker
Date: 17 Jan 13

Dear Steve

Thank you for visiting yesterday. I have been in contact with SLE, about showing them your device. They expressed great interest and have asked me along for next Friday, to enable their product specialist being available to join in. My aim is to get the device mounted on a SLE ventilator, to show a complete, ready-made solution. I will brief Viamed on the outcome. Yourself or Steve Nixon?

Viamed should be able to follow-up with SLE at Arab Health. It will be the same (and the right) people that I am meeting Friday. They didn't have any negative reaction to the device being from Viamed.

Europlaz remain keen to establish a supply agreement with Viamed. Acceptance and marketing by Viamed will add credibility to our sensor. It was certainly easier now to get interest from SLE, compared to when we showed up with the sensor on its own. And, the sensor would add a valuable option for the analyser.

Kind regards

Frede

Summary of meeting with Europlaz, 16/1/13

Europlaz operate automated production machines that can manufacture 10,000+ flowsensors per shift. Should the demand arise, they can double this with an additional shift.

The production process places the platinum wire onto the pins automatically and extremely accurately, using a video monitoring system to determine exact placement as part of the QA process. The tension of the wire is also controlled automatically with a very high repeatability.

The result is a sensor that Europlaz claim to be the most accurate on the market.

Europlaz are currently manufacturing sensors compatible with SLE, GE, Acutronic and Heinen & Lowenstein. They state that they are also capable of manufacturing Dräger compatible flowsensors.

The SLE compatible flowsensor with sidestream sampling port will cost in the region of £11-£12 per sensor for orders of 1000 per year.

They have modified the design of the SLE flowsensors to reduce the weight by around 50% by replacing the metal retaining rings with plastic ones and coring out the sensor, resulting in a weight of 7.5g. The GE sensor weighs 12.5g.

The SLE flowsensor has been extensively tested on test apparatus, but also needs some clinical testing. Frede has discussed this with Steve Nixon, who is arranging to have them trailed in a clinical application.

Europlaz are willing to manufacture these for Viamed with the Viamed name or logo moulded into the body of the flowsensor. They actively encouraged this and would like to make it as a Viamed product, with Viamed applying the CE mark.

Europlaz are meeting with SLE to discuss using the flowsensor in conjunction with a Viamed VM-2500-S CO2 monitor and would like Viamed to also speak directly with SLE to work towards ‘approving’ the flowsensor for use wit both the Viamed VM-2500 and SLE’s range of vents.

Feedback From Keith

From: Keith Taylor
To: Steve Hardaker
Date: 30 Jan 13

Hi Steve

Today I visited Andy Alford, Respiratory Tech, SCBU, Derriford Hospital to show/discuss the combination flow sensor with C02 sampling port. This SCBU use SLE 5000's with Drager capnographs. He cleared up a couple of points that we had recently discussed. The SLE 5000 can be switched between HFO mode and various other ventilation modes and EtCO2 readings cannot be obtained when in the HFO mode.
He told me both Drager and Philips use Oridion Microstream EtCO2 FilterLine H Airway Adapter Sets (a sample of which will be posted to you tomorrow). As you will see from the sample, the sample line is an integral fixed part of the airway adaptor (no Luer lock connection).
I will research a couple more SLE users and feed the info back to you.

Regards
Keith

From: Keith Taylor
To: Steve Hardaker
Date: 23 Jan 13

Hi Steve

I have contacted 4 hospitals icw SLE flowsensors and C02 measuring.
1/ Royal Shrewsbury have 2 SLE vents which are rarely used and are being replaced by Drager. The Tech, Peter Keen says they never measure C02 despite having a capnograph. He last bought a reusable SLE sensor 2 years ago at £122.00
2/ Southmead. Gill Taylor, the Equipment Sister is off till Thursday and the unit was so busy I could not speak to anybody else. The Tech (also the Clinical Engineering Manager) Paul Derman was working at another hospital.
3/ Whipps Cross. I spoke to the SCBU Matron who said they always monitor ETC02 on every ventilated patient. Price unavailable as Buying Sister is off duty.
4/ Royal Cornwall. Measure C02 sometimes. She guesses about 40-50% of their ventilated Neonates will have their ETC02 measured and only at the Consultant's request. I phoned back later in the day for the sensor prices, which is £96.00/box 5.
As and when I get more info I will pass it on.

Regards
Keith