Investigation into Stability Issues with MAX-16 Oxygen Sensors

The following MAX-16 oxygen sensors were returned to Viamed from a customer with a reported failure concerning long-term stability issues. They were investigated under Viamed job number SRS63950:

- MAX-16 s/n YC46003106
- MAX-16 s/n YC46003111

The sensors were installed in 2 separate Nellcor Puritan Bennett NPB840 ventilators and were soak tested over a period of a few hours in 100% oxygen to ascertain their stability.

Test method

The following describes the ventilator settings during the hospital's own testing in the engineer's own words:

> *We put the sensor in a NPB840 vent with the following settings – dry circuit with no chambers or humidifiers. We did not change any settings. We used a bellows type test lung.*
>
> *I have reproduced the fault with a different vent with everything else remaining the same*
>
> *Mode – BILEVEL*
>
> *Freq – 30 BPM*
>
> *PEEP HIGH – 38cmH20*
>
> *PEEP LOW – 14cmH20*
>
> *Time at HIGH – 1.2sec*
>
> *Rise Time 50%*
>
> *Oxygen – 100%*
>
> *I am not sure what the gas flow is in this mode*

The sensors calibrated initially, but after approximately 3 hours in 100% oxygen the instrument generates an oxygen sensor alarm and fails.
The instrument's error log reports "Bad O2 sensor - out of range". This failure is repeatable with the suspect sensors.

When OEM Covidien sensors are installed and the test repeated, the error is not generated.

The engineer returned the sensors to Viamed for investigation and we conducted a series of tests in a flow of oxygen at 1 L/min in a circuit designed to prevent air from being drawn into the circuit.

Results

Serial No	Output mV, t=0	Output mV, t=3h	Deviation
YC46003106	58.5	57.6	-1.54%
YC46003111	58.7	57.7*	-1.7%

*Sensor YC46003111 was connected to a voltmeter for the duration of the test. After 3 hours when the reading had settled at 57.7mV, the meter was disconnected then re-connected to temporarily change the loading on the sensor, at which time the output spiked up to 65.9mV and slowly fell over the next 2 minutes to 60.0mV. It took a full 5 minutes to return to a stable output.

Conclusion

The MAX-16 sensor specification quotes a stability of “less than 0.5% of full scale over an 8 hour period.” Based on that test criteria, both these sensors are faulty.

Both sensors were replaced with sensors from a different batch: XD46310070 and XD46310071, which were subject to the same test procedure over an extended period of 5 hours with the following results:

Serial No	Output mV, t=0	Output mV, t=5h	Deviation
XD46310070	62.06	62.01	-0.08%
XD46310071	58.94	58.41	-0.9%*

*Whilst sensor XD46310071 is not within the quoted specification of 0.5% of full scale, it performs significantly better than the sensors that were returned from the customer. The customer is going to test these in a NPB840 and report back how they performed, hopefully providing some useful information regarding the acceptable tolerance of the NPB840.

Sensors are to be returned to Maxtec for investigation and to determine whether further action is required.

Viamed and the customer concerned will monitor the situation with regards to sensors that Viamed has supplied.