DESIGN VERIFICATION OF THE RESPIRATORY SENSOR IN THE ALVBOV V101 REV A

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ORIGINATOR:	Marat Yevtukhov, Oleg Zagreblenny
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APPROVALS	
______/Dr. Alex Deas/____________ Project Leader	____30th Nov 2010_______ Date
______/Dr. Vladimir Komarov______ Quality Officer	____ 30th Nov 2010___________ Date

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Revision History

Revision	Date	Description
A1	1st Nov. 2010	Initial report issued for review: this is a complete repeat of previous verification due to a firmware changes.
A2	9th Nov 2010	Internal review complete
A3	13th Nov 2010	Issued for external review
A4	15th Nov 2010	Figure 1 added for clarity, showing sensor position.
A5	29th Nov 2010	Proof reading.
A6	30th Nov 2010	Full release approved

Acknowledgement is made to the Baltic Assessment Institute for the test and verification tasks reported herein.

Acknowledgements

A special thanks and our deep gratitude is due to Dr. Philip James, Emeritus Professor of Medicine, Department of Surgery, University of Dundee, for proposing this method of using thermal changes to measure respiratory rate, and advising Deep Life in this area. Dr. James is a leading light in diving medicine for over 40 years, who's work improved the safety of helium use offshore and developed oxygen treatment. Dr. James' work continues in Tayside, Scotland a tradition started by John Scott Haldane, of the Haldane family - the lairds of Gleneagles, who first explained the reason for the administration of oxygen as a treatment in the British Medical Journal in 1917. John Haldane devised the first apparatus to administer 100% oxygen and took it to the front during WW1 to treat soldiers who had been gassed. John Haldane also left his mark in diving by developing the method of staged decompression to avoid decompression sicknes.

Table of Contents

1 Purpose and Scope

The document describes the complete re-assessment carried out on the function and behaviour of the Respiratory Rate (RR) sensor located in the Deep Life OR ALVBOV PFD, following a firmware change.

The RR sensor is used directly to monitoring the diver for the effects of CO2, and is also used as a compensating parameter in determining end of exhale CO2, scrubber life and scrubber health.

The work affects critical safety functions, and is a verification report within Quality Procedure QP-20 and QP-24.

2 SIL Assignment

The SIL assignment of the overall system is SIL 3, reported in SA_SIL_Assessment_241208.pdf, and the respiratory rate sensor is a SIL 1 subsystem within that: it is augmented by other sensors to provide the SIL 3 function.

3 Requirements

3.1 Safety Requirements

The Deep Life Mantis system was checked for all safety requirements where the function involves respiratory rate, and the following requirements were identified under categories: PPCO2 Related, Carbon Dioxide Level related, and PPO2 related:

Mantis Item Number	*Category*	*Description*
0000580	PPCO2 Related	Active monitoring of respiratory parameters shall be provided
0000571	Carbon Dioxide Level related	Scrubber life shall be monitored
0000570	Carbon Dioxide Level related	Scrubber health shall be monitored
0000717	Diver Physiology related	Respiratory parameters shall be measured

3.2 Functional Requirements

The functional requirement within Mantis Item 580 is to detect the respiratory rate with ±5% accuracy, for respiratory rates from 5 bbm to 40 bbm, with tidal volumes of 0.2 lpm to 6 lpm.

The functional requirement within Mantis Item 571 is to determine the tidal volume for RMVs over the range 7.5lpm to 90lpm, with an accuracy of ±20%.

The respiratory rate is used as a warning and alarm indicator directly by the rebreather.

The tidal volume is used indirectly as a scrubber life indicator, in combination with other parameters including ambient temperature, respiratory rate, and gas mixture.

3.3 Environmental Requirements

The respiratory sensor and associated electronics control module shall operate under the following conditions (all expressed on Mantis):

- Storage temperature -30°C to +70°C
- Operating temperature range of 4°C to 34°C.
- Electronics operating temperature 0°C to +50°C
- Humidity 10% to 100% RH, non-condensing but breathing loop may be fully flooded
- Ambient pressure of 0.5 to 61 bar (600msw) absolute
- Vibration range of 0 to 60Hz, with amplitude ±2.5mm (5mm peak to peak), 6G.
- Helium gas environment at the above pressures.
- Maximum rate of pressure change 4 bar / minute

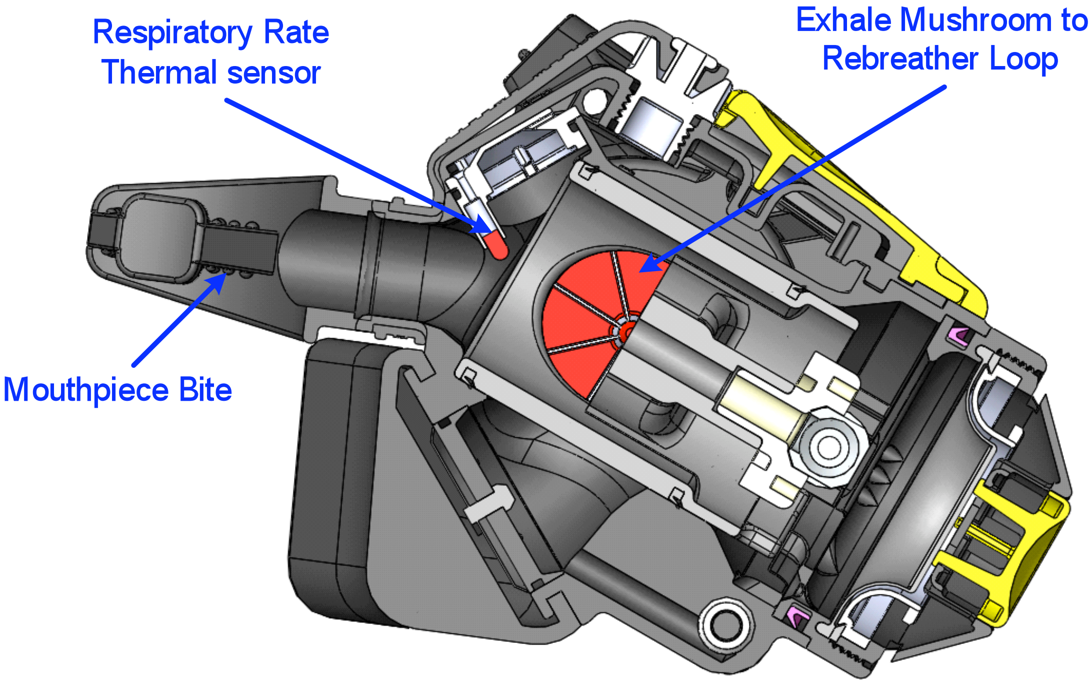


Figure 1: Cross section of ALVBOV Version 101 Rev A showing the position of the thermal sensor used for respiratory rate measurement. The above image shows a mouthpiece: the position of the sensor remains the same whether a mouthpiece or oro-nasal mask is used.

4 REVIEW OF DESIGN DATA

The respiratory sensor design was managed within the overall process stipulated in Deep Life Quality Procedure QP-20: this requires formal modelling and independent verification.

4.1 Respiratory Rate (RR) Measurement

Several methods for monitoring Respiratory Rate (RR) was investigated through to trial implementation and verification:

1. Use of differential pressure sensors located within the breathing loop, relative to ambient pressure. These provide to be unreliable as components, and subject to false signals from speech, operation of underwater tools, purging and other conditions. As a result, this approach was dropped.
2. Temperature sensing ahead of the CO2 scrubber. This produces a good quality signal but has lower amplitude and slower response than placement of a temperature sensor in the mouthpiece.
3. Temperature sensing in the mouthpiece. The method was advised by Prof. James when he was Director of the Wolfson Hyperbaric Medicine Unit of the University of Dundee Medical School, who had carried out extensive work with divers and separately, in respiratory sensing. This method was found to work well under noisy conditions, and was adopted by the project.

An NTC thermistor is used as a temperature sensor, shown in Figure 1, to measure the difference in temperature of exhale and inhale gases. The sensor is located in the ALVBOV. The output from the sensor is processed by the MCU in the PFD to calculate the respiratory rate. The MCU applies an Infinite Impulse Response band pass filter to remove high frequencies which appear from diver's breath or speech, and low frequencies due to ambient conditions.

4.2 Use of RR in Tidal Volume Measurements

A near-linear relationship is known between tidal volume and heart rate but that between tidal volume and RR is complex and non-linear. The relationship to heart rate is used by some dive computers. For example see Vai F, Bonnet JL, Ritter P, Pioger G, "Relationship between heart rate and minute ventilation, tidal volume and respiratory rate during brief and low level exercise.| Pacing Clin Electrophysiol. 1988 Nov;11(11 Pt 2):1860-5 online on http://www.ncbi.nlm.nih.gov/pubmed/2463559 with capture date of 20th Oct 2010 is used in some Uwatec dive computers. This study and others confirms there is no significant correlation between VO2 and RR, that the correlations between HR and VE, Vt and RR varied from one individual to another but nevertheless, the correlation coefficients were positive for VE and Vt, while they were negative for RR. Sensing respiratory rate is reported to be insufficient for responsive pacing at exercise onset, but sensing respiratory volumes (Vt, VE) should give satisfactory results.

Other references to these relationships include: W. Beaver and K. Wasserman, "Tidal volume and respiratory rate changes at the start and end of exercise", J Appl Physiol 29: 872-876, 1970; this paper is significant because the application is that of a monitor, which detects the effect of changes, including ventilation changes resulting from hypercapnia.

The tidal volume in the Deep Life rebreathers is determined by measuring the oxygen injected into the breathing loop, by measuring oyxgen injector flow: the relationship between oxygen metabolised is linear with RMV up to the Owles point, and after that point the increase in RMV above linear flow which occurs in unfit divers has the effect of overestimating the correction needed, effectively lowering CO2 limits for these divers. This flow data is compensated for the changes in volume that result from depth changes, to give RMV, which is then divided by the RR to give the tidal volume for the diver. For the dual rebreather, the data is combined as the sum of both channels, by summing the flow data. This calculation pipe means that if there is an error in the RR measurement, then there will also be an error in the tidal volume measurement and the end of tidal CO2 measurement.

4.3 Respiratory Rate Algorithm Review

The algorithm that calculates respiratory rate applies the following steps to the thermal sensor readings taken from the ALVBOV mouthpiece:

1. The thermal sensor values are read every 200ms and passed through a fourth order low pass filter defined by the recursive function:
   T_lp_out(n) = **A0***T_thermistor(n) + **B1 *** T_lp_out(n - 1) + **B2 *** T_lp_out(n - 2) +
   + **B3 *** T_lp_out(n - 3) + **B4 *** T_lp_out(n - 4)
   Where: **A0** = **1.07968*10^-3**
   B1 = **3.27492**
   B2 = -4.02192
   B3 = 2.19525
   B4 = -0.44933
   n is the sample number from the input or output arrays
   These values correspond to a fourth order low pass filter with the time constant of 5 samples * 200 ms = 1 second, which is 60 breaths per minute.

2. A 2^{nd} order derivative then calculated from the filter output.

3. Every ten seconds the number of 2^{nd} order derivative sign changes are counted, for a rolling period of 30s and the value taken to be the RR.

The formulae are expressed as a formal model in Simulink which acts as the formal specification for the respiratory rate calculations. These are recursive mathematical functions. They are implemented directly and not implemented using recursion because recursive calls are not permitted in the code of safety systems (MISRA C, SPARK Ada).

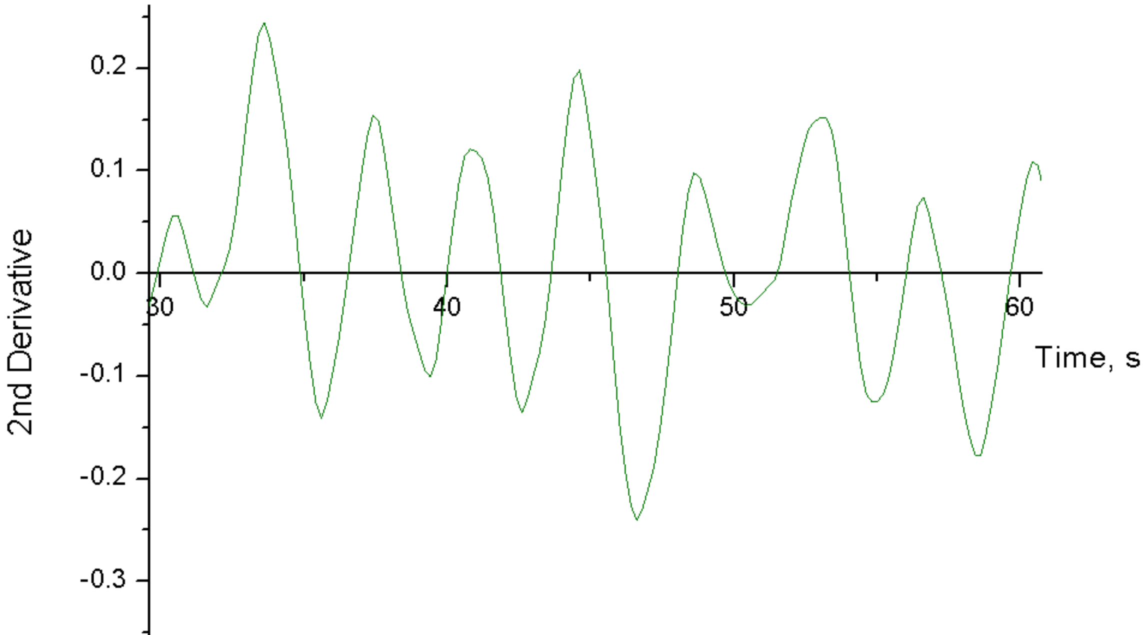


Figure 2: Example of the 2^{nd} order derivative sign changes following application of the algorithm over a period of 30 seconds. The respiratory cycles can be clearly identified from zero crossings and match the observed cycles of the test subject, an adult male. The Respiratory Rate is 16 bpm in this case.

5 EQUIPMENT

Instrument	Serial Number	Calibration
OR ALVBOV PFD	101 Rev. A	-
Cooled volume	N/A	-
Heated volume	N/A	-
Thermometer probe	224992F33	Checked on melting ice and boiling water prior to test.
Timer iPhone Stopwatch	-	-
Chamber and breathing simulator facility for pressure and vibration tests	See CO2 DV reports	See CO2 DV reports: the pressure cycle tests were performed as part of the CO2 test series.

6 METHOD

The samples of the ALVBOV supplied had been subject to the thermal conditioning and salt water exposure specified in EN 14143:2003.

The performance of the sensors depends critically on a difference between the ambient temperature and the breathing gas temperature.

Extensive machine testing was carried out previously, under the EN 14143:2003 Table 4 test conditions, with a 4C ambient temperature. That test data was reviewed in this assessment and it was concluded that the breathing simulator test conditions cover the range of normal use, but not boundary conditions. The focus of this report, verifying the function of the respiratory rate sensor, is an examination of the boundary and worst case states

To cover the boundary conditions, the following tests were performed using the ALVBOV:

1. Male rest respiration at room temperature.
2. Male rest respiration at 5°C inhale gas temperature.
3. Male rest respiration at +50°C inhale gas temperature.
4. Respiration with speech.
5. Respiration with loud acoustic noise environment.
6. Respiration with low frequency vibration as may be produced by underwater pneumatic tools, propellers and thrusters.

The resting respiratory rate is considered the worst case because it is shallow. Tests 4, 5 and 6 are combined with Tests 1, 2 and 3 above.

In each test an adult male starts breathing through the ALVBOV. Every 200mS an ADC performs a conversion of the thermistor output. Data from the ADC is logged in a Micro SD card in the PFD. Then log is read from the PFD and the data is analysed.

A selection of test divers was used that corresponds to typical commercial and rebreather divers that the equipment is designed for. Four adult males from 35 to 55 years old were tested, weights from 70kg to 93kg, height 1.74 to 1.78m, non-smokers, not suffering from any respiratory disease. There was no material difference noted between subjects; a random sample of these results are shown for each test. The speech is the “Quick brown fox” rhyme and diver selected random speech. The environmental requirements were reassessed using a breathing simulator in a pressure chamber, a vibration table and other equipment.

7 RESULTS FROM EMPIRICAL TESTS

7.1 Rest Respiration, Room Temperature, Quiet then Acoustic Noise

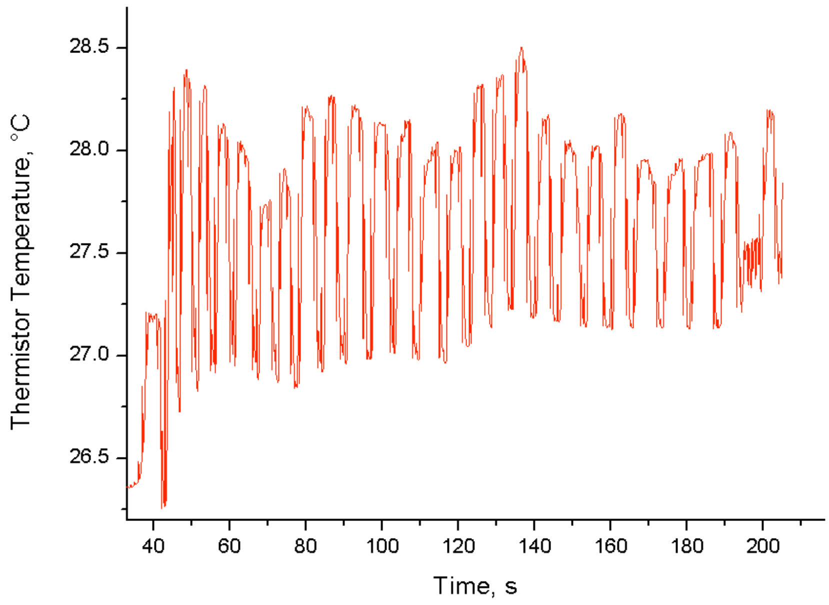


Figure 3: Original temperature data from the thermistor, showing the respiratory cycles which match the observed cycles, with speech from the "diver" one cycle from the end, including start up noise.

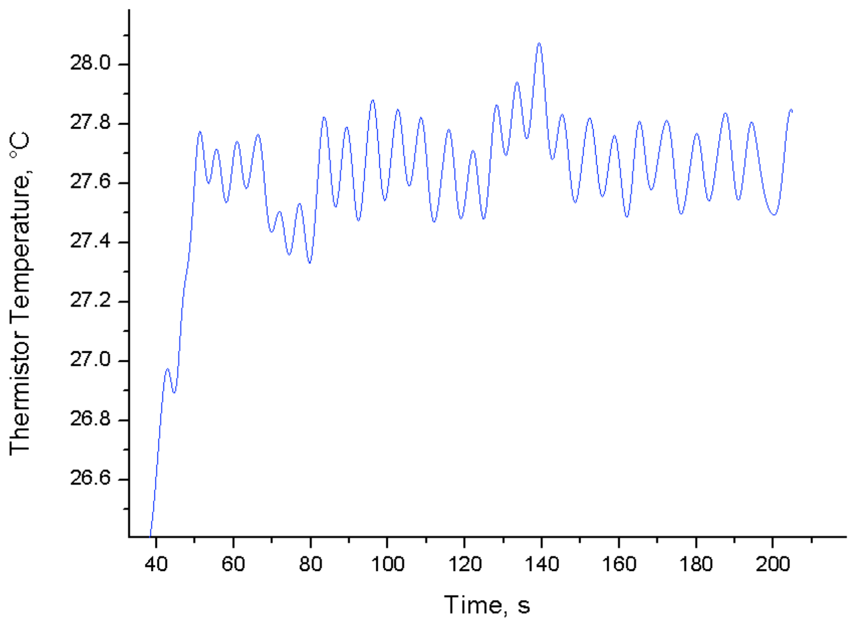
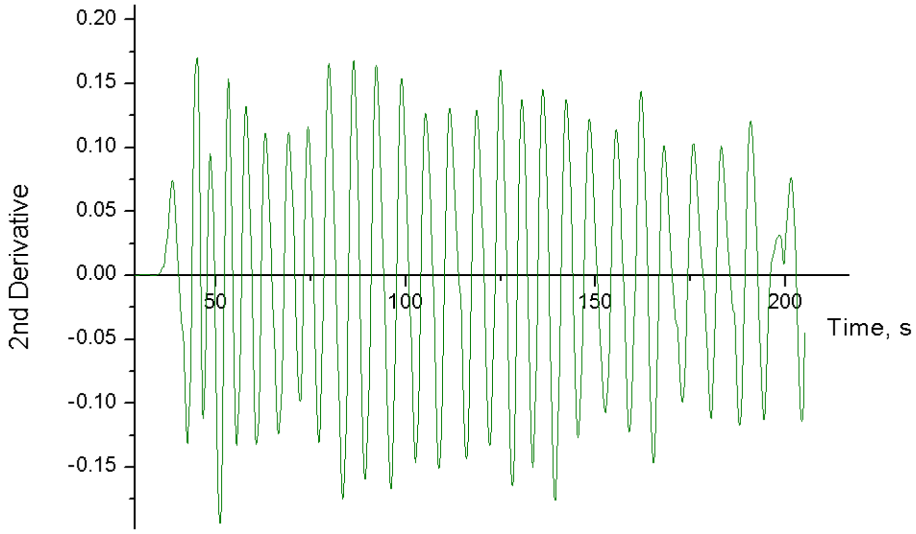
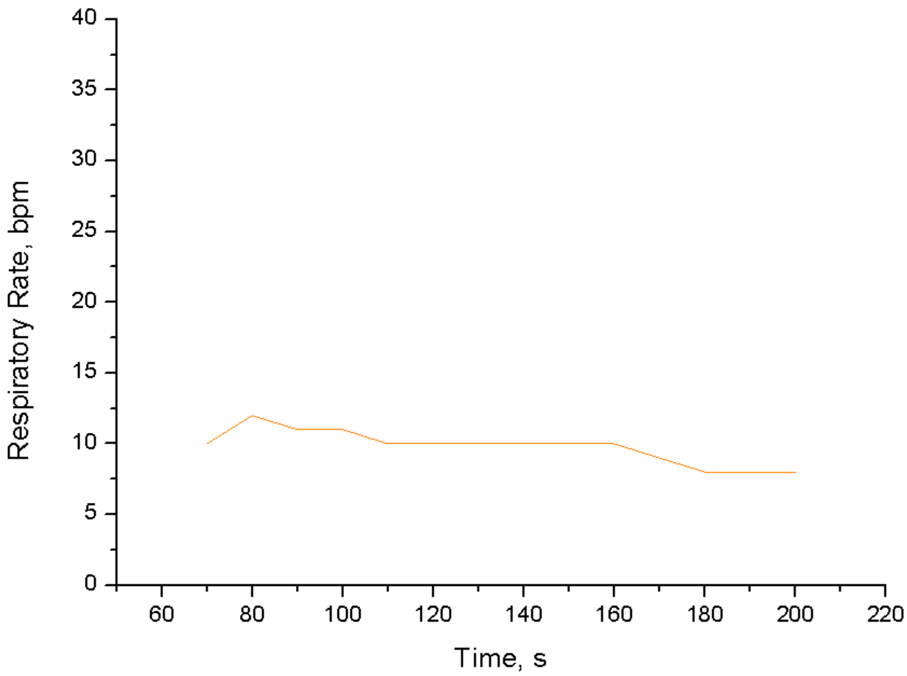


Figure 4: Fourth order low pass filter with the cut off frequency of 1Hz is applied to the original signal, see **Figure 3**



<u>Figure 5:</u> 2nd order derivative applied to thermistor data from the fourth order low pass filter, see **Figure 4.**

The count of the 2nd order derivative sign changes was started from the time of 40s for a rolling period of 30s in steps of 10s



<u>Figure 6</u>: Respiratory Rate obtained from the analisys of the 2nd order derivative sign changes over the period of 70s to 200s

The Respiratory Rate observed by watching chest movements and timing them using a timer over the same period was from 9 to 11 bpm. This matches the calculated values.

7.2 Rest Respiration, Temperature switch from 21°C to 5°C, Quiet then Noise

This test included a sudden switch from an ambient room temperature of 21°C to ambient temperatures of 5°C. This was achieved by switching the inhale breathing hose directly to a cooled volume[1].

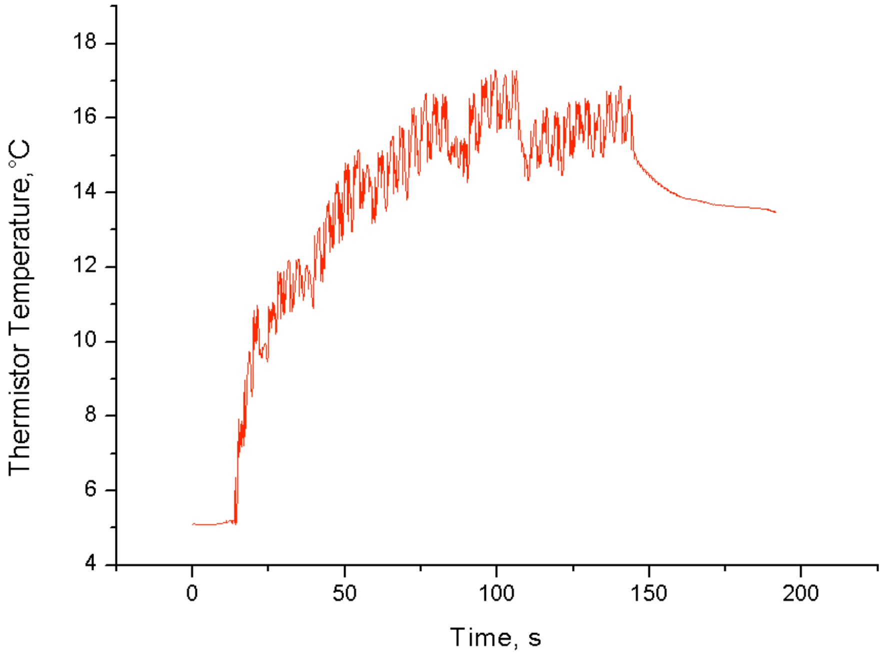


Figure 7: Original temperature data from the thermistor, showing the respiratory cycles which match the observed cycles, with speech from the "diver" including start up noise.

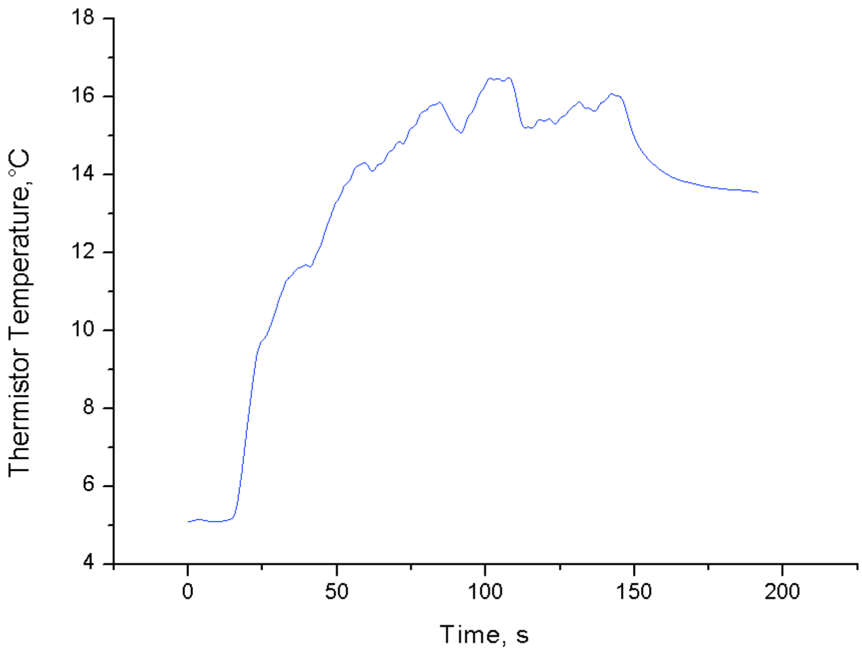


Figure 8: Fourth order low pass filter with the cut off frequency of 1Hz is applied to the original signal in **Figure 7**

[1] The cooled volume is an item of test equipment, comprising a monitored freezer space with air inlet and outlet.

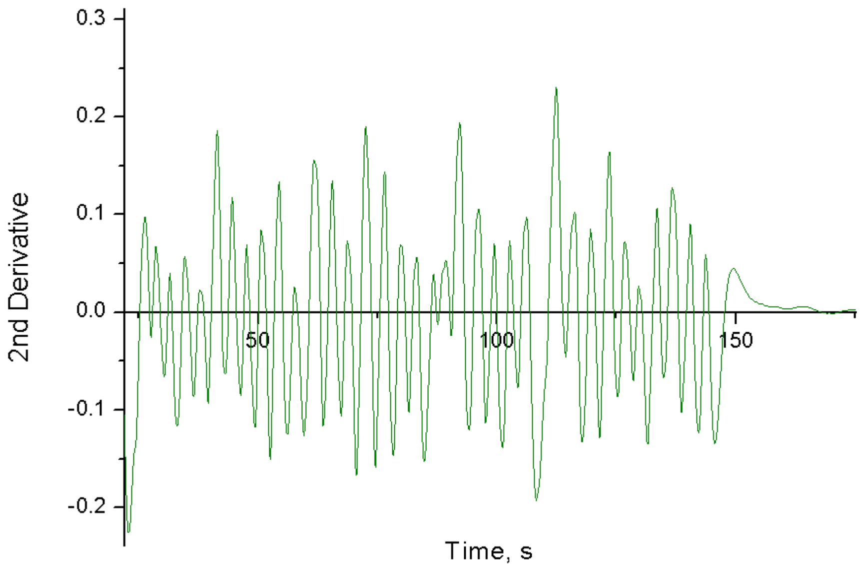


Figure 9: 2nd order derivative applied to thermistor data from the fourth order low pass filter in Figure 8.

The count of the 2nd order derivative sign changes was started from 60s into the test, for a rolling period of 30s in steps of 10s

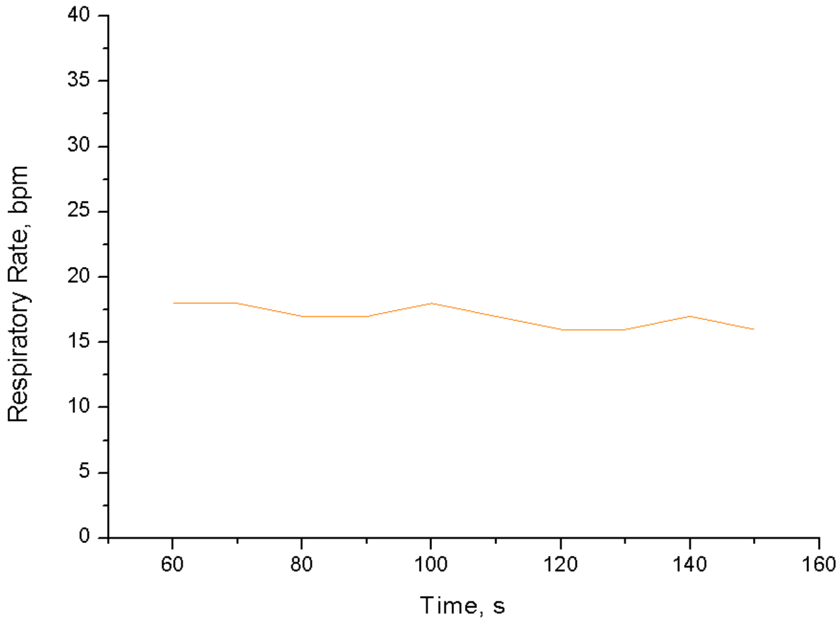
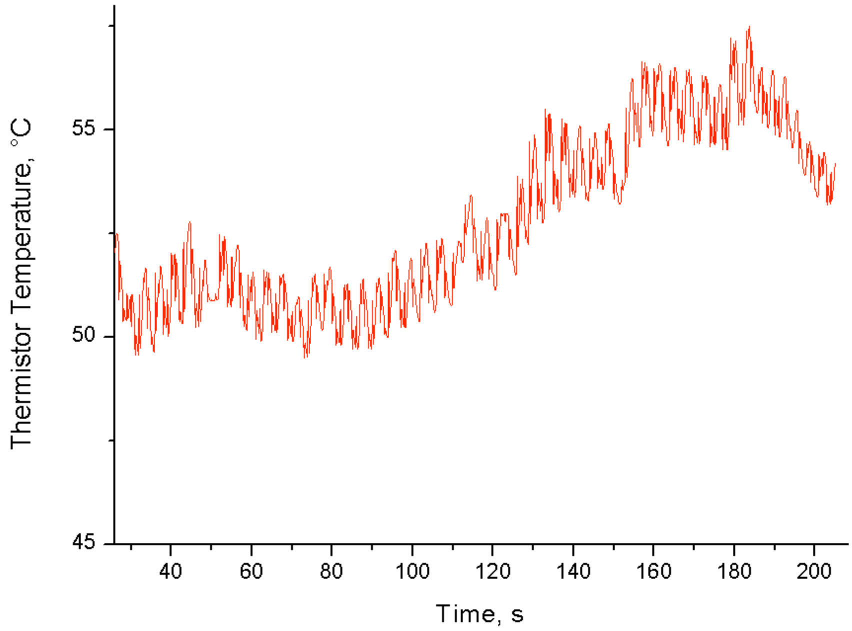


Figure 10: Respiratory Rate obtained from the analisys of the 2nd order derivative sign changes over the period of 60s to 170s

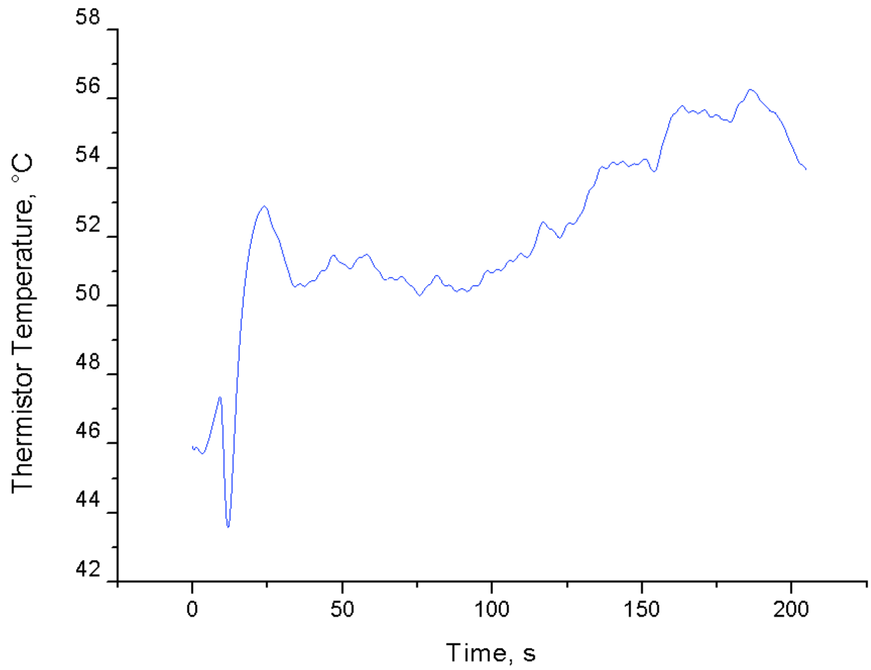
The Respiratory Rate observed by watching chest movements and timing them using a timer over the same period was around 17 bpm. This matches the calculated values above.

7.3 Rest Respiration, Temperature switch from 21°C to 50°C, Quiet then Acoustic Noise

The test including a sudden switch from an ambient room temperature of 21°C to ambient temperatures of 50°C. This was achieved by switching the inhale breathing hose directly to a heated volume. Adult male subjects were used.



<u>Figure 11:</u> Original temperature data from the thermistor, showing the respiratory cycles which match the observed cycles, with speech from the "diver".



<u>Figure 12:</u> Fourth order low pass filter with the cut off frequency of 1Hz is applied to the original signal in Figure 11

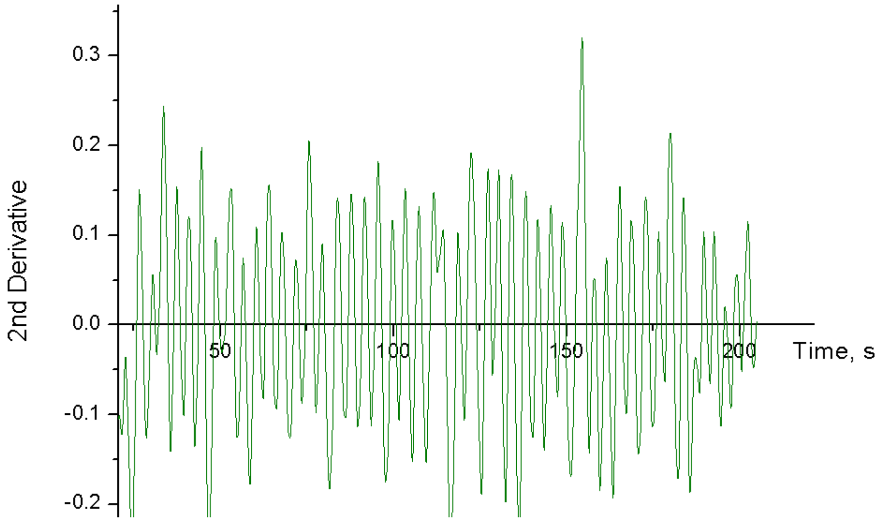


Figure 13: 2nd order derivative applied to thermistor data from the fourth order low pass filter, in Figure 12.

The count of the 2nd order derivative sign changes was started from the time of 60s for a rolling period of 30s in steps of 10s.

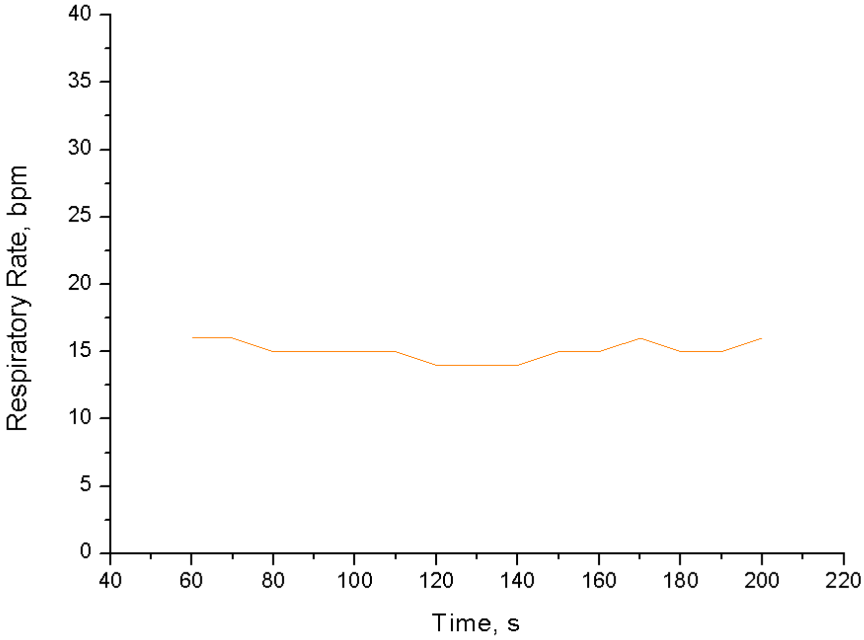


Figure 14: Respiratory Rate obtained from the analysis of the 2nd order derivative sign changes over the period of 60s to 200s

The Respiratory Rate observed by watching chest movements and timing them using a timer over the same period was around 15 bpm. This matches the calculated values above.

7.4 Environmental: Pressure, Pressure Changes, Vibration, Helium

Tests were performed using a breathing simulator, with heating of the exhaled gas to 32C, with up to 6G of vibration, in heliox gas mixtures at depths from 0 to 100m. No dependence was observed on these environmental conditions: i.e. there were no additional zero crossings from the 2nd order derivative as a result of these conditions.

8 CONCLUSIONS

Requirement	Description	Compliance
8.1 Safety		
• ***Mantis 0000580***	FMECA V6 Section 11.6 requires active monitoring of respiratory parameters shall be provided.	YES
• ***Mantis 0000571***	FMECA V6 Sections 11.1 (Scrubber Not Fitted), 11.3 (Scrubber Exhausted), and 11.4 (Scrubber Bypass) require scrubber life shall be monitored and this uses RR.	**YES**
• ***Mantis 0000570***	FMECA V6 Sections 11.1 (Scrubber Not Fitted), 11.2 (Scrubber Physically Damaged, affecting gas X-section), 11.3 (Scrubber Exhausted), and 11.4 (Scrubber Bypass) require scrubber health shall be monitored and this uses RR.	**YES**
• ***Mantis 0000717***	FMECA V6 Section 18.11 requires respiratory parameters shall be measured, and user shall be warned when these move outside normal or safe ranges. RR is a primary parameter that is monitored.	**YES**
8.2 Functional	Detect the respiratory rate with ±5% accuracy	**YES**
8.3 Environmental		
• Storage temperature	-30°C to +70°C	**YES**
• Operating temperature	4°C to 34°C	**YES**
• Electronics operating temperature	0°C to +50°C	**YES**
• Humidity	10% to 100% RH, non-condensing	**YES**
• Ambient pressure	0.5 to 61 bar (600msw) absolute	**YES**
• Vibration range	0 to 60Hz, with amplitude +/-2.5mm (5mm peak to peak), 6G	**YES**
• Helium gas environment	At the above pressures	**YES TO > 100m**
• Pressure change rate	4 bar / minute	**YES**

The Respiratory Rate sensor system in the ALVBOV Version 101 Rev A meets the design intent in all aspects. The accuracy appears to be an exact match with respiratory rate, to the accuracy of the firmware clock (i.e. within 0.01%).