Quality Assurance Program

Quality is taken very seriously. The quality assurance program is independently certified annually by the FDA, European and Canadian regulatory bodies and conforms to:

ISO 9001:2008
U.S. FDA: 510(k) No. K952736
Europe: Annex II of Medical Device Directive 93/42/EEC
Canada: ISO 13485:2003

Mandated for medical devices, industrial and diving products manufactured by Analytical Industries Inc. comply with the above quality standards.

A formal written assessment report is required for every product returned from the field. Our approach to customer service is proactive one, not only does Analytical provide customers with a copy of the assessment report but we routinely contact them to discuss and educate, and in many cases ourselves as well.

Historically, less than 1% of the sensors shipped are returned to Analytical Industries Inc. for warranty claims, and, of that figure less than one-half are determined to have manufacturing defects. Assessing these returns along with internal manufacturing yields has enabled Analytical Industries Inc. to continually improve our products and secure additional business.

Analytical Industries Inc.
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Analytical Industries Inc.

Oxygen Sensors

Applied to

Closed Circuit Rebreathers

Company Profile

Analytical Industries Inc. was founded by individuals whose experience included the development (original and recent patents), pioneering the application of electrochemical galvanic sensors and refining the manufacturing process. Formed in 1994, Analytical Industries Inc. started with a clean sheet of paper, 60 years of experience and devoted their first year to R&D with the objective of advancing existing sensor technology.

The result provided Analytical Industries with competitive advantages in terms of sensor performance, life and reliability. Combined with uncompromising standards for quality, customer support and service Analytical Industries Inc. has become a recognized worldwide supplier of electrochemical oxygen sensors to the industrial, medical and diving industries.

Following this strategy, Analytical Industries Inc. and their Advanced Instruments business unit has become the preferred supplier of electrochemical based oxygen analyzers to global companies in the field of industrial gases, petrochemical products, natural gas, beverages, metals, ventilators, anesthesia machines, diving and rebreathers, the latter includes supplying the U.S. Navy with O_2 sensors for the MK16 rebreather since 1998.

Principles of the Galvanic Oxygen Sensor

Materials: Membranes sealed to a plastic body encapsulate anode, cathode and a base electrolyte. Wires conduct outputs from anode (-) and cathode (+) via an external circuit typically a PCB. The PCB consists of various electrical connectors, a resistor-thermistor temperature compensation network and is attached to the rear of the sensor.

Operation: The galvanic fuel cell sensor is actually an electrochemical transducer which generates a current (µA) signal output that is both proportional and linear to the partial pressure of oxygen in the sample gas. Oxygen diffuses through the front sensing membrane and reaches the cathode where it is reduced by electrons furnished by the simultaneous oxidation of the anode. The flow of electrons from anode to cathode via the external circuit results in a measurable current proportional to the partial pressure of oxygen (PO_2). The sensor has an inherent absolute zero, therefore, no oxygen no signal output.

Signal Output: A higher or lower signal output within the specified output range offers no performance advantage. The PCB network converts the signal output from current (µA) to (mV) signal output. Signal output can influenced (and compensated) by several factors such oxygen concentration, temperature and pressure.

Temperature: Influences the signal output at the rate of 2.54% per ^{0}C. Ambient (gradual) changes in temperature can be compensated within the $\pm$2% accuracy specification by processing the signal output through an appropriate resistor-thermistor temperature compensation network. Step (rapid) changes should be avoided or allow at least 15 minutes for the signal output and temperature compensation network to equalize. The effect depends on the temperature change inside the breathing circuit. Some rebreather manufacturers compensate electronically to eliminate the effect of temperature.

Pressure: Influences signal output on a proportional basis. Tests show sensors are accurate at any constant pressure up to 30 atm provided the sensor is pressurized equally front and rear. A pressurized sensor must decompressed gradually (similar to a human).

Altitude: Dives of 200 ft. produce an error of 0.3% and do not have a significant effect on the signal output.

Humidity: Water vapor according to Dalton's Law of Partial Pressure exerts its own partial pressure when added to a gas stream, thereby, reducing the partial pressure of oxygen and the reading displayed. Conversion charts are available for air calibration which define the effect of humidity on the oxygen level.

Carbon Dioxide (CO_2): An acid gas that reacts with the sensor's base electrolyte. The effect on the sensor varies with exposure time. Exposure to CO2 for 15-20 minutes followed by flushing with air has virtually no effect on the sensor. Repeated exposure of 3-4 hours can result in a temporary loss of signal output. Continuous exposure has a dramatic effect on sensor life. For example a sensor with a normal 12 month life in air at 77º and 1 atm that is continuously exposed to 5-6% CO_2 will expire in 3-4 weeks.

Life: In theory, sensor life is limited by the amount of anode material and signal output. A higher signal output yields a shorter life because the anode is being consumed at a faster rate. In reality, however, the Expected Life specification considers the signal output range. In general, sensor life is inversely proportional to changes from the specified parameters: oxygen concentration (air 20.9%), temperature (25ºC/77ºF) and pressure (1 atm/bar).

Load: The sensor does not tolerate reverse current flowing into the sensor. No load is recommended, but 10K Ohm is the maximum permissible. Exceeding a load of 10K Ohm produces an error in linearity.

Calibration: Follow the recommendations included in the rebreather manufacturer's Owner's Manual. Perform at or near operating conditions, e.g. if measuring dry compressed gas, calibrate with same or if calibrating in air use a conversion chart which defines the effect the humidity (above) and temperature on the oxygen level.

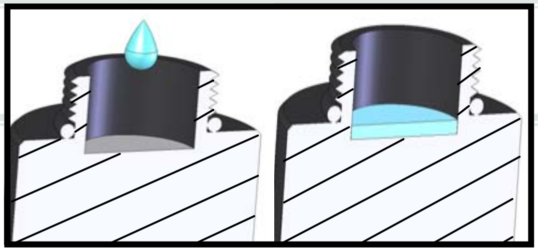
Mode of Failure: Defect or Misuse

Preface: Historically, when a sensor does not function beyond its warranty period the issue of what is a defect as opposed to misuse arises. The intent here is to explore the effects and possible causes objectively.

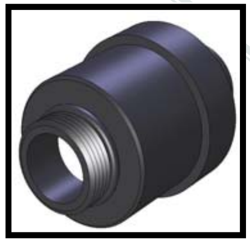
Normal Operation: When operated at or near the specified parameters (see sections of Signal Output and Life) signal output and anode consumption remain constant over 80-90% of the sensor's expected life. As the signal output decreases it falls below the lower limit of the electronic design and eventually preventing calibration of the electronics.

Storage: Prolonged exposure above 50ºC (122ºF) can weaken the seals that secure the front and rear membranes to the sensor and acerbate submicroscopic pin holes (that escape a stringent leak test that every sensor passes) in the laminated front sensing membrane both of which may result in electrolyte leakage in the shipping bag. Each degree above the specified parameter of 25ºC (77ºF) reduces expected sensor life by increasing the internal rate of reaction which accelerates the consumption of the anode.

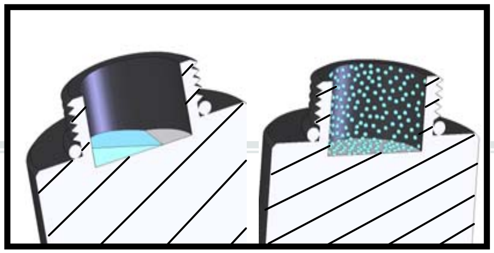
Liquid / Moisture: Condensation on the sensing surface of the sensor reduces the signal output by blocking the diffusion of oxygen into the sensor and is mistakenly categorized as a sensor defect. The reality, there is no damage to the sensor, simply remove the liquid and the signal output returns.



Complete Coverage: Signal output decreases 12mV to 10mV (17%) after 20 minutes.



Orientation is important



Partial Coverage: Signal output, no change.

Shock: Can compromise electrical connections, break wires or cause a tear in the sensing membrane resulting in erratic readings. Dropping a sensor from 3 ft. onto a carpeted concrete office slab (a) reduced signal output by at least 25% or worse (b) dislodged the anode contacted a cathode wire thus creating a short circuit.

Erratic Oxygen Readings: Can result from a) shock; b) an aged sensor or well used sensor that is 2-3 years from its manufacture date (see Serialization/ Date Code); c) blocking the "breather holes" in the PCB at the rear of the sensor prevents the pressure surrounding the sensor (front and rear) from equalizing; d) a load in excess of 10K Ohm; e) repeated exposure to CO_2 of 3-4 hours can result in a temporary loss of signal output, see Carbon Dioxide CO_2

Higher than Expected Oxygen Readings: Result when minute pinholes (see Storage) or tears in the sensing membrane allow additional unwanted oxygen to enter the sensor. The most common causes are the shock of dropping a sensor or pressing on the sensing surface in an attempt to remove liquid. Exposure to CO2 can also cause a temporary increase in the oxygen reading.

Quality Control of Manufacturing

Design: After years of experience working with and studying competitive galvanic oxygen sensors, Analytical Industries has focused on advancing the quality and reliability along with performance of their sensors by simplifying the assembly process and eliminating sources of internal contamination. As a result, there are no welds, epoxy or dissimilar metals inside the Analytical Industries sensor.

Leak Test: A stringent proprietary test that detects microscopic pin holes in the laminated membranes and marginal membrane seals. 100% of the base electrolyte sensors are subjected to this stringent procedure and must pass successfully, otherwise they are scrapped.

Output Testing: Following leak test, all sensors sit for a predetermined period of time to allow the signal output to stabilize. Next, the current output (µA) of every sensor is tested and recorded.

Diving sensors are then equipped with a PCB that includes the appropriate electrical connector and the temperature compensation network which converts the current (µA) signal output to (mV) output. Each sensor is tested 3x more times during the remainder of the assembly process before the sensor is accepted and serialized.

Dive Pressure Test: Analytical Industries tests all diving sensors for output in air (20.9%) and linearity at 100% oxygen, and, under 1.6 ATA using a proprietary automated system developed in collaboration with rebreather manufacturers and instructors.

As illustrated below, individual test reports are generated for every sensor and identify the sensor by model, serial number, date and time tested, accompany every sensor shipped. The print out documents the chamber pressure (PO2 psi), signal output (mV) and whether the sensor pass/failed (Result) within an error of <$\pm$3%.

Model: PSR-11-39-JD
Serial No.: 90734789
Date: 07/29/09 13:02

PO2 psi	mV	Result
2.99	12.14	PASS
14.06	57.11	PASS
24.69	99.64	PASS

Serialization / Date Code

Oxygen sensors have a finite life. Understanding the date code embodied in the serial number is critical to determining the age or manufacture date of a sensor, maximizing the benefit of the warranty period and helping users avoid buying and/or diving with aged sensors. For example, the serial number above 90734789 breaks down as follows:

Digit #1:	9 identifies the year of manufacture as 2009
Digits #2,3:	07 identifies the month of manufacture as July
Remaining:	Sequentially issued for uniqueness

As the result of a number of issues related to the use of aged sensors, Analytical Industries will add this definition to the sensor's.

Warranty Policy

Coverage: Under normal operating conditions, the sensors are warranted to be free of defects in materials and workmanship for the period specified in the current published specifications.

Analytical Industries in their sole discretion shall determine the nature of the defect. If the item is determined to be eligible for warranty we will repair it or, at our option, replace it at no charge to you. This is the only warranty we will give and it sets forth all our responsibilities, there are no other express or implied warranties. The warranty period begins with the date of shipment from Analytical Industries Inc. This warranty is limited to the first customer who submits a claim for a given serial number. Under no circumstances will the warranty extend to more than one customer or beyond the warranty period.

For info call 909-392-6900, fax 909-392-3665 or e-mail diveaii@aii1.com. To make a warranty claim, you must return the item and postage prepaid to:

Analytical Industries Inc.
2855 Metropolitan Place
Pomona, Ca 91767 USA

Exclusions: This warranty does not cover normal wear and tear; corrosion; damage while in transit; damage resulting from misuse or abuse; lack of proper maintenance; unauthorized repair or modification of the analyzer; fire; flood; explosion or other failure to follow the Owner's Manual.

Limitations: Analytical Industries Inc. shall not liable for losses or damages of any kind; loss of use of the analyzer; incidental or consequential losses or damages; damages resulting from alterations, misuse, abuse, lack of proper maintenance; unauthorized repair or modification of the analyzer.

What We Have Learned . . .

The effects of the topics listed below are discussed in detail in the preceding pages and in the interest of brevity are not duplicated.

Challenging Application: When it comes to the closed circuit rebreather the oxygen sensor is exposed to an environment that plays to more of the device's weaknesses than its strengths. That is not to say the oxygen sensor is not suited for this application, but getting the most out of the oxygen sensor requires working around the limitations, understanding the device and a little discipline in terms of handling and maintenance.

Preventive Maintenance: Our investigation has yielded a surprising number of cases involving diving with old sensors, the lack of regular sensor replacement and failure to follow the rebreather manufacturer's calibration procedure.

Design: Currently there are no regulations governing rebreather manufacturers which accounts for the various designs on the market.

Temperature: The CO_2 scrubber generates heat which keeps the temperature inside the rig around 90ºF. The design should locate the oxygen sensor in the coolest location possible.

Liquid: The heat generated by the CO_2 scrubber also produces a continual source of condensation which does not damage the sensor itself. Again the design should position the oxygen sensors to minimize or prevent the collection of water on the sensing surface.

Electronics: The quality of the computer systems used to control today's rebreathers vary from rig to rig. If the electronics are flooded or malfunction a charge can be sent to the oxygen sensor resulting in permanent damage to the sensor, see Load. Electrical connectors should gold and kept watertight. However, using rubber-type caps to seal the connections at the back of the sensor can cause an unwanted pressure differential between the front and back of the sensor.

Recommended Maintenance: Rebreather Owner's Manuals repeatedly warn users to follow recommended maintenance procedures for post dive of opening and flushing the rig, proper inspection and lubrication of o-rings and seals to prevent leaks which could expose the oxygen sensors to oxygen levels of 70-100% and exposure to CO_2.

Shock: Even contributors to the internet forums admit the rigs (and the components inside) are not accorded the proper handling, an issue for electronics as well as the oxygen sensor.