Manufactured under a
Quality Management System
certified to:

- MDD/93/42 EEC, Annex II
- ISO 13485:2003
- ISO 9001:2008

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Analytical Industries Inc.

Electrochemical Galvanic Oxygen Sensor

(Percentage Range)

Fact Sheet

Purpose:

Analytical Industries Inc. intent here is to educate current and potential users of electrochemical galvanic oxygen sensors on the construction, operating principles and considerations, possible causes of failures, distinguishing a manufacturing defect from an application related failure, quality control techniques, date coding and the warranty policy.

About the manufacturer:

Analytical Industries Inc. is a global leader in the design, manufacture and sale of oxygen gas sensors and analyzers. Our technological expertise is demonstrated by innovative product design, sophisticated manufacturing and quality control techniques, and, world class customer support. The company was formed in 1994 and has become the preferred supplier to major manufacturers of industrial gases and petrochemical products; natural gas producers; OEM of medical ventilators; and, since 1998 the U.S. Navy's MK16 underwater closed circuit rebreather used by Seal and Ordinance units making us a recognized leader in a number of industries.

Sensor Construction:

Delicate sensing membranes approximately 1/2 mil thick and more robust 2-4 mil rear membranes are sealed to a precision machined HDPE tube (body) and encapsulate the anode, sensing electrode (cathode) and proprietary electrolyte formulas. Wires conduct the outputs from the anode (-) and cathode (+) inside the sensor and are soldered to an external PCB which is then attached to the rear of the sensor. The sensor generates a current or micro-amp (uA) signal output requiring a simple PCB. To aid the design of OEM devices the PCB normally include a resistor-thermistor temperature compensation network which converts the uA signal output to mV.

Principles of the Galvanic Oxygen 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 meaning no oxygen no signal output.

Normal Conditions & Applications: The information that follows is based on conditions of 20.9% oxygen concentration, 25°C (77°F) and 1 atm in applications involving inert gases including helium and hydrogen, non-condensing hydrocarbon gases, carbon monoxide and most mixed gases.

Signal Output: Determined along with the internal rate of reaction by the thickness of the sensing membrane which in turn is dictated by the application's need for faster response or longer life. The acceptable range of a sensor's signal output from its nominal value is ±30% due to slight variations in membrane thickness and the sealing process. A higher or lower signal output within the specified output range offers no performance advantage. Signal output can be influenced by several other factors as described below:

Temperature: Influences the signal output and expected life at the rate of 2.54% per °C. Ambient (gradual) changes in temperature are compensated within the ±2% accuracy specification. Once calibrated at ambient conditions, the accuracy is ±5% over the operating temperature range. Step (rapid) changes in temperature require at least 30 minutes for the signal output to equalize. The influence of temperature can be eliminated electronically when addressed in the design phase.

Pressure: Influences signal output and expected life proportionally. Galvanic oxygen sensors are accurate at any pressure up to 30 atm provided the pressure is constant, applied or relieved gradually (similar to the human lung) and equal at the front and rear of the sensor.

Altitude: As a partial pressure device, changes in elevation simply requires calibration. 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.

Noncompatible Background Gases: CO2 levels above 1% require an XLT acid based electrolyte sensor for continuous use. Standard base electrolyte sensors can be used in CO2 intermittently (15-20 minutes) with minimal effect, provided the sensor is flushed with air for an equal period of time immediately following exposure to CO2. H2S has a more dramatic effect regardless of the type of electrolyte and must be removed or scrubbed to less than 10 PPM in the sample gas. Oxidizing gases produce their own signal output in addition to oxygen preventing analysis. Qualify background gases with the manufacturer.

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.

Expected Life: Life is determined by the rate at which the anode is consumed. A higher signal output consumes the anode at a faster rate. A higher signal output is the normal trade-off involved with a faster response time (thinner front sensing membrane) versus longer life. We use proprietary methods to control the rate of anode consumption.

Changes from normal conditions influence the signal output: oxygen concentration and pressure have a proportional effect; whereas, the temperature effect is 2.54% per °C. For example, when operated continuously and exposed to sample gas at 35°C with all other factors remaining constant, a sensor will demonstrate a 25% [(35°C-25°) x 2.5%] reduction in life.

Storage: With the exception of the XLT acid electrolyte sensors, references to storage life, storage recommendations and shelf life are not indications of perishable life and are intended to encourage use before the individual sensor warranty expires. Guidelines for storage:

1. A sensor stored in its original shipping package and within $\pm$5% of normal conditions will function for the storage and expected life periods specified.
2. If it becomes necessary to remove the sensor from the original shipping packaging, simply seal the sensor in a heavy duty zip-lock type plastic bag.
3. To extend the expected life, store below normal conditions.
4. CAUTION: Store above 50°C or 122°F on an intermittent basis only;
   Do not allow sensors to freeze;
   Do not store sensors in atmospheres devoid of all oxygen.

Calibration: Guidelines for achieving the accuracy specification:

1. Ensure the oxygen reading is stable before calibration, allow sensors just removed from the shipping package to stabilize in air for 15 minutes;
2. Calibrate at the temperature and pressure of the sample gas;
3. Galvanic oxygen sensors do not require zero or two point calibration;
4. Use a known source of clean air or a certified span gas approximating 80% of the full scale measuring range for measurements below 30% oxygen;
5. Calibrate with 100% oxygen for measurements above 30% oxygen;
6. Calibration intervals can extend up to 3 months in normal applications (varies with background gases, user quality or PM programs), whereas, medical and diving applications require calibration before each use.
7. If measuring dry compressed gas, calibrate with same dry gas or if calibrating in air use a conversion chart which defines the effect the humidity (above) and temperature on the oxygen level;
8. Follow the recommendations included in the Owner's Manual.

Notes: ______________________________

Do's & Don'ts: ______________________________

Failures: Defect or Misuse

Preface: When a sensor does not function beyond its warranty period or in many cases its expected life, the question arises as to whether the root cause is a manufacturing defect or misuse (application conditions or operator error).

Normal Mode of Failure: When operated at or near normal conditions the signal output and anode consumption remain constant over 90% of the sensor's expected life and drops off dramatically at the end. As the signal output decreases it falls below the lower limit of the span calibration range and prevents calibration of the device.

Possible Manufacturing Defects: Despite our extensive and ever evolving quality control program (described herein) we have yet to attain zero defects. Since the oxygen sensor has no moving parts, post production defects generally manifest themselves as out-of-the-bag failures as follows:

1. Leakage of liquid electrolyte visible through or upon opening the sealed shipping package can result from a marginal seal, a pin-hole in the sensing membrane or in rare instances mishandling (shock) by inventory or transportation personnel.
2. Inability to pass the initiation calibration can result from of the shock of being dropped, a marginal electrical connection, leakage of electrolyte or in rare instances internal contamination (refer to Quality Control section).

Possible Field Misuse:

Temperature: When operated continuously and exposed to sample gas at 35° C with all other factors remaining constant, a sensor will demonstrate a 25% [(35°C-25°) x 2.5%] reduction in life.

Prolonged exposure above 50ºC (122ºF) in storage or use:
1. Increases the anode consumption rate which reduces expected life;
2. Can compromise the front (thinner and more susceptible) and rear membrane seals to the sensor body resulting in the leakage of liquid electrolyte;
3. In rare instances acerbate sub-microscopic pin holes in the laminated front sensing membrane that pass leak testing but can later leak electrolyte.

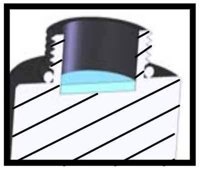
Pressure: Sudden changes in pressure even at low pressure 15-20" water column create a venturi effect vacuum that can compromise a seal or tear the delicate front sensing membrane resulting in the leakage of electrolyte which manifests itself as first an increase in the oxygen reading followed by a drop and the inability to calibrate. Possible causes include holding a finger over the vent line to confirm flowmeter operation, a defective valve or pressure cycle.

Noncompatible Background Gases: As recommended previously, qualify background gases with the manufacturer. Acid gases (CO_2), sulfur compounds (H_2S) and oxidizing gases, (chlorine Cl) can dramatically reduce expected life by contaminating internal sensor components or corroding electrical connections which gives the false indication the sensor's signal output has failed.

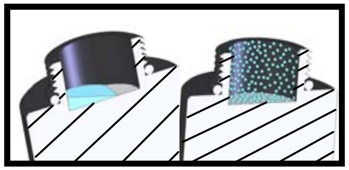
Shock: Dropping a sensor can compromise electrical connections or cause a tear in the sensing membrane. Actual testing has shown the shock of dropping a sensor from 3 ft. onto a carpeted concrete office slab floor dislodged internal components resulting in a minimum 25% reduction in signal output, and, worse case a short circuit and complete loss of signal output.

Erratic Oxygen Readings: Possible causes include:
1. A sensor whose anode is nearly consumed regardless of whether due to normal use or exposure to abnormal conditions;
2. Shock of being dropped;
3. Fluctuating pressure in the sample line;
4. A sensor that has experienced a sudden change in pressure;
5. Different pressure at the front and rear of the sensor which can occur with screw-in mounting or if the "breather holes" in the PCB are blocked;
6. Exposure to unqualified corrosive gases or liquids which can compromise solder joints and electrical connections;
7. Repeated 3-4 hour exposure (non-XLT) to CO_2 without flushing with air;
8. Pressing on the sensing surface when cleaning or removing liquid;
9. A load in excess of 10K Ohm.

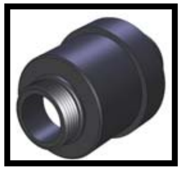
Liquid and Moisture: Condensation on the sensing surface of the sensor reduces the signal output by blocking the diffusion of oxygen into the sensor and is mistakenly categorized as a sensor defect. The reality, there is no damage to the sensor, simply remove the liquid and the signal output returns.



Complete Coverage: Signal output drops from 12mV to 10mV 17% in 20 minutes.



Partial Coverage: No change.



Orient sensing surface down or horizontally.

Liquids should not be confused with heavy hydrocarbon vapors which can condense at lower temperatures, cover the sensing surface and prevent the gas sample from diffusing into the sensor which gives the false indication the sensor's signal output has failed.

An inline coalescing filter is a suitable remedy for gas streams with a relatively small amount of liquid. Analytical Industries Inc. has designed analyzers with an innovative sensor and sample handling system dubbed the "LD (Liquid Drain) Series" to specifically address applications with large amounts of liquids.

Higher than Expected Oxygen Readings: Possible causes include:
1. Calibrating before the oxygen sensor (reading) stabilizes regardless of whether installing a new sensor or checking an in service sensor;
2. Poor quality calibration gas;
3. The sensing membrane and/or seals are compromised and additional unwanted oxygen enters the sensor which can result from a number of causes such as sudden changes in pressure, exposure to elevated temperature, the shock of being dropped, pressing on the sensing surface during cleaning or removing liquid;
4. Exposure to CO_2 can cause a temporary increase in the oxygen reading.

Quality Control

Quality is taken very seriously and is continually being improved upon and expanded. 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. are subject to the same QA System.

Innovative Design: With years of experience studying and developing galvanic oxygen sensors, Analytical Industries has advanced the quality, reliability and performance of our sensors by simplifying the design and assembly processes. The lack of welds, epoxy or dissimilar metals inside the Analytical Industries' sensor eliminates sources of internal contamination, a major reason we have developed a reputation for high quality products.

Proprietary Manufacturing Processes: The prevention of contamination is continued over to employee training, tight controls and inspection of the manufacture, preparation and automation of sub-assemblies.

Leak Test: Once the front (sensing) and rear membranes are attached, every sensor undergoes a stringent and proprietary test that detects holes in the laminated membranes and marginal seals. Sensors that do not successfully pass the leak test are scrapped.

Current (uA) Output Stability Test: Following leak test, the sensor is stabilized for a predetermined period of time. They are then connected in batches of 50-60 to an automated apparatus, designed and built entirely in-house, that tests the sensor's signal output in air, linearity when exposed to 100% oxygen and stability during a 5 minute exposure to 100% oxygen. A report is generated that documents which sensors or positions pass and which fail, and, if the sensor is temperature compensated (as are the majority of medical and diving sensors) the report specifies the circuit that optimizes the performance of each individual sensor.

Final Assembly: At critical points the signal output of each sensor is reconfirmed with independently certified test equipment before the sensor is accepted and serialized. Medical and diving sensors are equipped with a PCB that includes a temperature compensation network (tailored to the signal output of each individual sensor for optimum performance) which converts the sensor's normal current (µA) signal output to a (mV) signal output.

Millivolt (mV) Output Stability Test: Medical and diving sensors typically involve a variety of secondary housings, connectors and as previously mentioned temperature compensation networks making them more complex and given the critical nature of the application dictated the need for further testing.

A second test apparatus similar to the Current (uA) Output Stability Test generates a paper and electronic data file that documents each sensors' (mV) signal output at 3 distinct test points after:

(1) Exposure to ambient air for 2 minutes, the output must be within published specification range;
(2) Exposure to 100% oxygen for 45 seconds, the output must be linear within ±2.5% of its theoretical value at 100% oxygen;
(3) Continued exposure to 100% oxygen for 5 minutes, where a reading is recorded every 3 seconds and the output must be stable within ±2.5% over the duration of the test. One reading outside the tolerance fails the sensor for the entire test.

Results are graphically presented as pass (green) or fail (red) for each sensor. Sensors that do not successfully pass all 3 tests are considered failures and scrapped.

Pressure Test: In general the use of industrial and medical oxygen sensors are governed by company managed QA Systems, however, sensors intended for use in underwater diving closed circuit rebreathers are controlled by individual consumers. Therefore, due to the critical nature and unique operating conditions, oxygen sensors intended for use in underwater diving closed circuit rebreathers are subjected to additional testing and labeling. Using a proprietary automated system developed in collaboration with rebreather manufacturers and instructors, each sensor's partial pressure (PO2) and (mV) signal output are tested under different application conditions:

1. Ambient pressure (ATA) in ambient air 20.9% oxygen (FO2);
2. Ambient pressure (ATA) in 100% oxygen (FO2), also confirms linearity;
3. Elevated 1.3 to 1.8 pressure (ATA) in 100% oxygen (FO2);

PASS indicates the signal output was accurate within ±2.5%.

A copy of this test report, see below, accompanies every rebreather oxygen sensor shipped. Since rebreather sensors are resold between users, a "DO NOT USE AFTER" date is included on the sensor label as a warning to all users.

1

Model: PSR 11-39-MD
Serial No.: 403221393
Date: 03/03/14 14:46

ATA	FO2	PO2	mV	Result
0.965	0.209	0.202	12.42	PASS
0.964	1.000	0.964	59.29	PASS
1.721	1.000	1.721	105.06	PASS

Dalton's Law: ATA x FO2 = PO2

Quality Reporting

Our QA System mandates as part of our post-market surveillance the preparation of a formal written assessment report summarizing our findings and disposition of every product returned from the field.

Not only does Analytical Industries Inc. provide customers with a copy of this report but we routinely find them to be a source of preventative/corrective action and continual improvement.

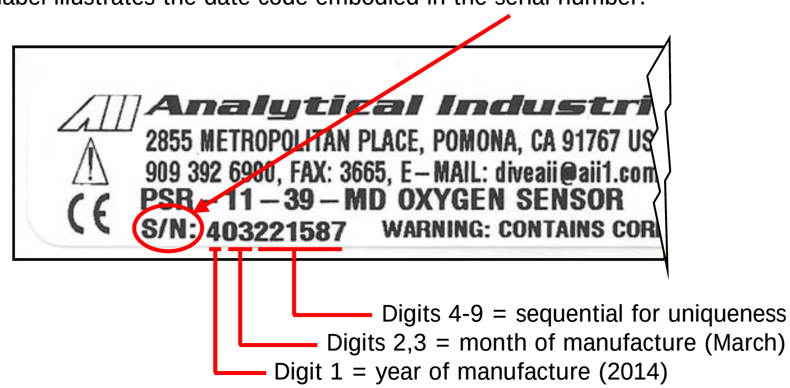
Further, the results of these reports on returns are compiled quarterly as are the results of our production Device History Records to identify trends as another source of preventative/corrective action and continual improvement.

Historically, the results of our examinations of returned sensors follow:

- 0.3% Manufacturing defect
- 0.4% No Indication of Failure
- 0.3% Damaged/Misused/Misapplied by Customer

Date Coded Serial Number

Oxygen sensors have a finite life that can vary with application conditions. Understanding the date code embodied in the serial number is key to determining the age of a sensor and maximizing the benefit of the warranty period. A typical label illustrates the date code embodied in the serial number.



Warranty Policy

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

Coverage: Under normal operating conditions, the sensors are warranted to be free of defects in materials and workmanship for the warranty period shown in the current published specifications. Analytical Industries Inc. in their sole discretion shall determine the nature, root cause of the defect and eligibility for warranty. If the product is 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 shipment date from Analytical Industries Inc. and 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.

Making a warranty claim, contact a customer service representative, see below, to discuss the circumstances surrounding your situation. Generally, determination of the root cause of a failure or warranty claim requires the product be returned (see Quality Reporting) freight prepaid to:

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

Contact Us: Telephone: 909-392-6900, Fax 909-392-3665
e-mail: sales-industrial@aii1.com, sales-medical@aii1.com,
or diveaii@aii1.com.

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.