



Analytical Industries Inc.
Advanced Instruments Inc.



ISO 9001:2008



EN ISO 13485:2012



MDD 93/42/EEC



Quality Assurance

... the extent of control applied to suppliers to ensure their product conforms to specified purchase requirements shall be dependent upon effect of the purchased product on the final product.

... the organization shall continually improve the effectiveness of the quality system and take action to eliminate the causes of nonconformities.

O₂ Medical

CCR Rebreathers

Industrial



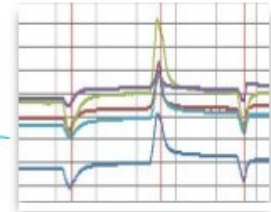
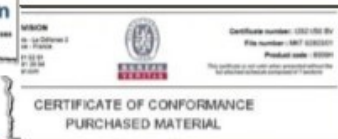
✓ Suppliers

Certified QA System

Conformance to Specifications

Incoming Inspection

Incoming Testing



✓ Pre-Assembly Prep

Eliminate internal contamination

Rigorous equipment PM program

Certified test equipment



Leak Test

100% of sensor seals are tested using a proprietary chemical process.

✓ OLOS-TC Automated μ A Test Protocol



| Sensor (1-60) | Output in Air (μ A) | Output in Air | Linearity to 100% O ₂ | Output at 100% O ₂ | Stability at 100% O ₂ | Temp Comp |
|---------------|--------------------------|---------------|----------------------------------|-------------------------------|----------------------------------|-----------|
| 1 | 60.3 | FAIL | PASS | PASS | PASS | 155 |
| 2 | 52.3 | PASS | PASS | PASS | PASS | 200 |
| 3 | 55.9 | FAIL | PASS | PASS | PASS | 175 |
| 4 | 51.5 | PASS | PASS | PASS | PASS | 200 |
| 5 | 52.9 | PASS | PASS | PASS | PASS | 200 |

To ensure reliable sensor performance, the key parameters are 100% tested, recorded and filed.


The OLOS Protocol goes next level by reading the unique current output of each individual sensor and selecting the temperature compensation network that optimizes the sensor's performance when the temperature changes.



✓ Work in Process Quality Control

Following each critical operation in the assembly process, the lot is tested 100% to confirm the signal output using equipment with calibration certifications.

✓ OLOS Automated mV Final Test Protocol



| Sensor (1-60) | Output in Air (mV) | Output in Air | Linearity to 100% O2 | Output at 100% O2 | Stability at 100% O2 |
|---------------|--------------------|---------------|----------------------|-------------------|----------------------|
| 1 | 11.5 | PASS | PASS | PASS | PASS |
| 2 | 12.0 | PASS | PASS | PASS | PASS |
| 3 | 11.0 | PASS | PASS | PASS | PASS |
| 4 | 11.5 | PASS | PASS | PASS | PASS |
| 5 | 12.3 | PASS | PASS | PASS | PASS |

The temperature compensation PCB converts the sensor's uA output to mV.

OLOS Final Protocol Phase #1 duplicates the initial test in lots of 60 sensors, above right.

OLOS Final Protocol Phase #2 again goes next level, below, by extending the stability test while the sensor is exposed to 100% oxygen.



| Sensor (1-60) | Output in Air (mV) | Specification Test Parameters | | Stability over 100 Readings | | Linearity to 100% O2 | Stability to 100% O2 | Stability to 100% O2 | | |
|---------------|--------------------|-------------------------------|----------|-----------------------------|-------|----------------------|----------------------|----------------------|-------|-------|
| | | Min Pass | Max Pass | Min | Max | | | 1 | 99 | 100 |
| 1 | 11.54 | 53.84 | 56.6 | 54.79 | 54.9 | PASS | PASS | 54.79 | 54.90 | 54.88 |
| 2 | 12.01 | 56.02 | 58.9 | 57.25 | 57.33 | PASS | PASS | 57.27 | 57.33 | 57.32 |
| 3 | 11.05 | 51.54 | 54.18 | 52.65 | 52.75 | PASS | PASS | 52.65 | 52.75 | 52.73 |
| 4 | 11.55 | 53.87 | 56.64 | 55.17 | 55.25 | PASS | PASS | 55.17 | 55.22 | 55.25 |
| 5 | 12.33 | 57.52 | 60.47 | 58.99 | 59.05 | PASS | PASS | 59.00 | 59.23 | 59.20 |

Quantifying stability in terms of deviation between Min and Max output and comparing Min and Max readings to the Specification parameters identifies the marginal of error of every sensor and prevent nonconformities from reaching users in the field.

Traceability is established by applying serial numbers sequentially to sensors that PASS all tests. OLOS prompts the operator for model, DHR job number, serial number range and generates a filename for electronic filing.



Analytical Industries Inc.
Advanced Instruments Inc.

✓ **Closed Circuit Rebreather O₂ Sensors**

Due to the critical nature and unique operating conditions, oxygen sensors used in underwater diving closed circuit rebreathers (CCRs) are subjected to similar stability testing plus additional testing at elevated pressure(s) of 1.3 to 1.8 ATA to simulate actual application conditions. utilizing a proprietary automated system developed in collaboration with rebreather manufacturers and diving instructors.

ATA = Pressure

FO₂ = Oxygen Concentration

PO₂ = Partial Pressure Oxygen

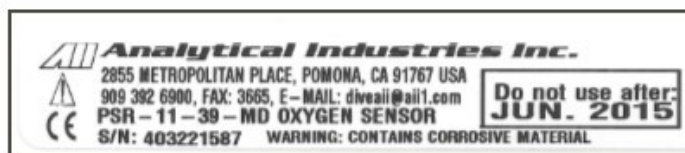
mV = milli-Volt Oxygen

PASS = $\pm 2.5\%$ of Specification

The actual test report accompanies every rebreather oxygen sensor shipped, see example right.

| 1 | | | | |
|--|-----------------|-----------------|--------|--------|
| Model: | PSR 11-39-MD | | | |
| Serial No.: | 403221393 | | | |
| Date: | 03/03/14 | 14:46 | | |
| ATA | FO ₂ | PO ₂ | 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: $ATA \times FO_2 = PO_2$ | | | | |

As added safety precaution in recognition sensors are resold between users, the label includes a "DO NOT USE AFTER" date as a warning to all users.



✓ **Summary:**

An uncompromising commitment to quality produces results:

. . . tangible, documented, traceable confidence in our product

*. . . competitive advantage for **Analytical Industries Inc.***

. . . most importantly increased customer satisfaction.