Analytical Industries Inc.

Technical Specifications

Accuracy:	< ±2% of FS range under constant conditions
Analysis:	0-100% oxygen
Application:	Anesthesia Respiratory Therapy Neonatal & Pediatric Incubators & Hoods Oxygen Therapy - Intensive Care Emergency Transport
Calibration:	Certified dry 100% oxygen or air after 8 hrs of use
Compensation:	Temperature
Connections:	1x16 mm thread or o-ring flow diverter
Controls:	Soft touch keypad for ON/OFF and Calibration
Dimensions:	2.72" x 4.1" x 1.35"; weight 7 oz. (196 grams)
Display:	3 digit LCD 1.1" x .625"; resolution 0.1% O_2
Flow Sensitivity:	None between 0.2 to 10 liters per minute
Humidity:	Non-condensing 0-95% RH
Linearity:	± 1% under constant conditions
Pressure:	Inlet - ambient or regulated; vent - atmospheric
Power:	(2) 1.5V AA alkaline batteries; 13,000 hrs of use
Response Time:	90% of final FS reading in 10 seconds
Sensitivity:	< 0.5% of FS range
Sensor:	AII-11-75-PO2
Sensor Life:	32 months in air at 25ºC and 1 atmosphere
Storage Temp.:	-20º to 60ºC (-4ºF to 140ºF) on intermittent basis
Temp. Range:	5º to 45ºC (41ºF to 113ºF)
Warm-up Time:	None
Warranty:	12 months analyzer; 12 months sensor

Options & Accessories

AII-11-75-PO2R Remote Oxygen Sensor (requires A-3654, CABL-1009)
FITN-1009 Tee Adapter
A-3675-1 Home Care Kit
A-3657-1 Dovetail Mounting Kit
HRWR-1075 Dovetail Female Clamp Pole/Shelf
HRWR-1157 Screwdriver
HRWR-1158 Lanyard
A-3657-1 Dovetail Mounting Kit

AII-2000 Palm O_2 Oxygen Analyzer

Easy user interface . . . one touch controls

Simple to use . . . accurate reliable results

One touch calibration . . . 100% O_2 or air

Long battery life . . . 13,000 hrs of continuous use

Advanced sensor technology

State of the art electronics

Certified Quality Assurance System

CE 0473

ISO 9001:2008

MDD 93/42/EEC Annex II as amended 2007/47/EC

ISO 13485:2003, Health Canada MDR

INTERTEK ISO 9001:2008

INTERTEK ISO 13485:2003

UKAS QUALITY MANAGEMENT 061

2855 Metropolitan Place, Pomona, CA 91767 USA ♦ Tel: 909-392-6900, Fax: 909-392-3665, www.aii1.com, email: sales-medical@aii1.com Rev 6/11

Analytical Industries Inc.

510(k) K952736 O2 Sensor
510(k) K053407 O2 Analyzers

EN 12598:1999 / ISO 7767: 1997
(Oxygen monitors for patient breathing mixtures – Particular requirements).

EC: Medical Device Directive: 93/42/EEC, Annex II as Amended by 2007/47/EC, Certificate #485CE

0473

ISO 9001:2008, Certificate #485

Authorized EC Representative:
RGV Lda.
Rua Jose Joaquim de Freitas, 247
2750-404 Cascais-Portugal

Health Canada: Medical Device Regulations, F-27/ SOR-98-282

ISO 13485:2003, Certificate #485B

Analytical Industries Inc. dba Advanced Instruments Inc.,
2855 Metropolitan, Pomona, CA 91767 USA.
Tel: 909-392-6900, Fax: 909-392-3665
Email: sales-industrial@aii1.com, Web: www.aii1.com

Instructions for Use

AII-2000 Palm O_2 Oxygen Analyzer

Table of Contents

1 Introduction

Congratulations on your purchase, these Instructions for Use describe the precautions, set-up, operation, maintenance and specifications of the AII-2000 Palm O2 Oxygen Analyzer.

This symbol means CAUTION – Failure to read and comply with the Instructions for Use could damage the device and possibly jeopardize the well being of the patient and/or health care professional.

Note: Analytical Industries Inc. cannot warrant any damage resulting from the misuse, unauthorized repair or improper maintenance of the device.

1.1 Indications for Use

The AII-2000 Palm O2 Oxygen Analyzer is intended to measure and display the concentration of oxygen in breathing gas mixtures. The intended use is only to verify, spot check or continuously monitor, oxygen concentrations in circumstances where the oxygen concentration is controlled and set by other medical device such as oxygen/air blenders, flow meters or other control device.

Users must read the following statements as they are essential to reducing the risk of use error due to ergonomic features of the device or the environment in which the device is intended to be used.

The devices as identified in Section 1.4 Declaration of Conformity have been designed and manufactured in such a way that when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or safety of the users or other persons.

Federal law restricts this device to sale by or on the order of a physician.

Conformity with essential requirements has been demonstrated by verifying the performance of the device under normal conditions, bench testing, pre-clinical and simulated clinical evaluations and determining that undesirable malfunctions constitute minimal risk to patients and users.

Particular requirements for sterilization do not apply to these devices. Do not sterilize, autoclave, liquid sterilize, immerse in any liquid or expose the device or accessories to steam, ethylene oxide or radiation sterilization.

The device is intended to be re-usable. Should the device or accessories come in contact with patient bodily fluids, either dispose of the device or clean with a soft cloth dampened with 70% isopropyl alcohol solution in water and allow the components to air-dry before re-use .

The device and accessories are not intended to transport or store any medicines, body liquids or other substances that can be administered or removed from the body, and, do not contain any latex, human blood derivatives, phthalates, carcinogens or other reproductive toxics.

Calibrate the device with 100% oxygen before using each day or after 8 hours of continuous use. In the event the device fails to calibrate or if the reading becomes, do not attempt to use the device. Contact the manufacturer for assistance.

Do not operate the analyzer near equipment capable of emitting high levels of electromagnetic radiation as the reading may become unstable.

In order to obtain optimum performance, the operation of the device must be performed in accordance with these Instructions for Use. Maintenance should be performed only by trained personnel authorized by the manufacturer.

Additional operating pointers are provided in Section 3.

1.2 Intended Use

The AII-2000 Palm O2 Oxygen Analyzer is intended to measure and display the concentration of oxygen in breathing gas mixtures. The intended use is only to verify, spot check or continuously monitor, oxygen concentrations in circumstances where the oxygen concentration is controlled and set by other medical device such as oxygen/air blenders, flow meters or other control device found in the following medical applications:

Anesthesia (refer to Section 5.2)
Respiratory Therapy – Ventilators, Respirators
Neonatal & Pediatric Incubators & Hoods
Oxygen Therapy - Intensive Care
Spot Checking Concentrator

1.3 Device Description

The AII-2000 Palm O2 Oxygen Analyzer can be positioned on a table top or pole (tripod wire stand and V-mount dovetail attachments are mounted on the back of the device) and are readily portable from one location to another. They provide continuous, fast, reliable and accurate oxygen measurements of up to respiratory care systems.

The device utilizes an electrochemical galvanic fuel cell type oxygen sensor of the type that is extensively used to measure oxygen concentrations from 0% to 100% in gas streams. Oxygen, the fuel for this electrochemical transducer, diffusing into the sensor through a gas permeable membrane reacts chemically at the sensing electrode to produce an electrical current output proportional to the oxygen concentration in the gas phase. The sensor has an absolute zero meaning that when no oxygen is present to be chemically reacted the LCD displays 00.0 oxygen.

The sensor's signal output is linear over the entire range, remains virtually constant over the specified useful life and drops off sharply at the end. The sensor itself requires no maintenance and is simply replaced at the end of its useful life like a battery. Inasmuch as the sensor is a transducer in its own right, its expected life is not affected by whether the analyzer is ON or OFF.

A battery powered state-of-the-art micro-processor converts the sensor's signal output representing the partial pressure of oxygen in the gas stream being analyzed. The resulting oxygen reading is displayed by a large easy to read backlit liquid crystal display (LCD) that has a resolution of 0.1% oxygen. The microprocessor is controlled from a keypad and provides system diagnostics and warning indicators for continuous monitoring that enhance both safety and effectiveness.

Prior to shipment, every device is thoroughly tested at the factory and documented in the form of a Quality Control Certification that is included in the Instructions for Use supplied with every device.

The manufacturer's contact information and serial number of this device can be found above the battery compartment cover on the rear of the device and in Section 2 Quality Control Certification.

In conclusion, Analytical Industries Inc. appreciates the opportunity to supply this device and anticipates many years of useful service.

1.4 Declaration of Conformity

Manufacturer:	Analytical Industries Inc. 2855 Metropolitan Place, Pomona, California 91767 USA Tel: 909-392-6900, Fax: 909-392-3665 e-mail: sales-medical@aii1.com, www.aii1.com
Authorized EC Representative:	RGV Lda. Rua Jose Joaquim de Freitas, 247 2750-404 Cascais-Portugal
Product:	AII 2000, AII 2000A, AII 2000HC, AII 2000 Palm O2 Oxygen Analyzers; AII 2000M Oxygen Monitor PSR Series Oxygen Sensors
Classification:	IIb
Directives:	Medical Device Directive 93/42/EEC, Annex II as amended by 2007/47/EC
Standards & Certificates:	510(k) K952736 O2 Sensors 510(k) K053407 O2 Analyzers EN 12598:1999 (ISO 7767: 1997) Oxygen devices for patient breathing mixtures – Safety requirements Medical Device Directive 93/42/EEC, Annex II as amended by 2007/47/EC, Certificate 485 CE ISO 9001:2008, Certificate 485 ISO 13485:2003, Cert 485A Medical Device Regulations, F-27/ SOR-98-282 (Canada)
Notified Body:	AMTAC Certification Services Limited Davy Avenue, Knowhill Milton Keynes MK5 8NL United Kingdom
CE mark affixed:	February 21, 2006

We hereby declare the above product meets the provisions of the directives and standards specified. All supporting documents are retained on the premises of the manufacturer.

Patrick Prindible, QA Manager

2 Quality Control Certification

Customer: _____ Order No. _____ Date: _____

Model: AII-2000 Palm O_2 Oxygen Analyzer S/N _____

Sensor: ( ) AII-11-75-PO2
( ) AII-11-75-PO2R (requires A-3654, CABL-1009) S/N _____

Electronics: A-1190 PCB Assembly Main Software Version _____

Accessories: BATT-1008 Battery, 1.5V AA Alkaline (Qty 2)
FITN-1112-1 Flow Diverter
P-0188 Manual, Instructions for Use ..... Included _____

QC Test:	PASS
LCD display 3-1/2 digits	_____
Battery symbol displays when battery is low	_____
Span adjustment ±10-30% FS with 100% oxygen calibration	_____
Following calibration with 99-100% oxygen and flushing with ambient air, oxygen reading as displayed by LCD 20.9% ±2%	_____
Span adjustment ±10-30% FS with air calibration	_____
Following calibration with air (20.9% oxygen) and exposing to 99-100% oxygen, LCD displays 100% ±2%	_____
Overall inspection for physical defects	_____

Options:	Item No.	Qty
	FITN-1009 Tee Adapter	_____
	FITN-1065 Nipple Universal	_____
	A-3675-1 Home Care Kit (A-3675, TUBE-1007)	_____
	A-3657-1 Dovetail Mounting Kit (A-3657, HRWR-1162)	_____
	HRWR-1075 Dovetail Female Clamp Pole/Shelf	_____
	HRWR-1157 Screwdriver	_____
	HRWR-1158 Lanyard	_____

Delivery:

3 Safety Warnings

ALWAYS follow the statements below as they are essential to reducing the risk of use error due to ergonomic features of the device or the environment in which the device is intended to be used.

- Only trained personnel who have read, understand and agree to follow the Instructions for Use should operate the device.
- Retain the Instructions for Use for future reference.
- Refer service needs to trained authorized personnel. Failure to do so may cause the device to fail and void the warranty.
- Inspect the device and accessories before operating and ensure: (a) there is no evidence of physical damage; (b) the sensor (particularly the sensing surface) and electrical connections are dry; and, (c) the sensor is installed and upstream from any humidifying device for accurate calibration and oxygen readings.
- Calibrate: (a) with a known source of dry 100% oxygen before using each day or after 8 hours of continuous use; (b) when the temperature or pressure of the operating environment changes; (c) if the oxygen sensor has been disconnected and reconnected; (d) after the battery or oxygen sensor has been replaced.
- Sampling flowing gas: (a) install the flow diverter and the tee-adapter in a vertical position as shown in Section 4.4 and (b) assure there is a tight fit between the flow diverter and tee adapter.
- Sampling static, ambient or controlled atmospheres such as incubators, oxygen hoods, tents, etc.: remove the flow diverter.
- Clean the device and accessories in accordance with Section 6.1.2**.**
- Battery replacement Section 6.2: (a) replace the batteries within twenty-four (24) hours of the battery symbol appearing on LCD display and (b) calibrate the analyzer after replacing the batteries.
- Oxygen sensor installation or replacement Section 6.3: allow the new sensor to stabilize for 15-20 minutes in ambient air before attempting to calibrate.
- Store the device by turning the power OFF and removing the batteries if the device will not be operated for over thirty (30) days.
- Attempt to repeat the procedure that caused a perceived malfunction and refer to troubleshooting hints in Section 7 before concluding the device is faulty. If in doubt, contact the manufacturer for assistance.

NEVER operate the device in any manner described below doing so may compromise the clinical condition or the safety of patients, users or other persons.

- If the reading is unstable or a malfunction is suspected.
- After the battery symbol appears in the LCD display.
- Near equipment capable of emitting high levels of electromagnetic radiation (EMI) or radio frequency interference (RFI).
- Expose the device; particularly the LCD display or sensor to sources of extreme heat, cold or excessive sunlight beyond the device's storage temperature range, refer to Section 8 for extended periods of time.
- In a gas stream with a vacuum greater than 14" water column.
- Immerse the device, oxygen sensor or coiled cable in any liquid.
- Outside of the parameters specified in Section 8 particularly at flow rates greater than 10 liters per minute - the backpressure generated produces erroneously high oxygen readings.
- Calibrate: (a) with 20.9% oxygen or room air with the intent of taking oxygen measurements at oxygen levels above 30% oxygen; (b) in a humidified gas stream or atmosphere; (c) without allowing a newly installed sensor to stabilize for 15-20 minutes in ambient air.
- Attempt to sterilize, autoclave, liquid sterilize, immerse in any liquid or expose the device or accessories to steam, ethylene oxide or radiation sterilization.
- In the presence of flammable anesthetic gases.
- Open the main compartment of the device, except to change the integral oxygen sensor.
- Open the oxygen sensor or probe the sensing surface, refer to Section 10 in the event the sensor should leak and someone comes in contact with the electrolyte from inside the sensor.
- Optional remote sensor with a cable that appears worn, torn or cracked, or, allow an excess length of cable near the patient's head or neck; secure it to the bed rail or other suitable object to avoid the possibility of strangulation.
- Allow the device or oxygen sensor to be serviced, repaired or altered by anyone except trained personnel – failure to do so may endanger the patient or damage the device rendering the warranty null and void.

4 Start-Up

4.1 Contents of Shipping Container:

The contents include:

- AII-2000 Palm O2 Oxygen Analyzer
- FITN-1112-1 Flow Diverter
- P-1088 Instruction for Use

Note: See section 6.5 for remote sensor option and Section 8.1 for optional accessories.

The device is shipped with the batteries and oxygen sensor installed at the factory and is ready for calibration and use.

Any optional equipment is secured in a plastic bags and stored next to the analyzer in the shipping container.

Inspect the box and contents for shipping damage. If any component appears damaged, do not attempt to operate the device and contact the manufacturer immediately, refer to section 9.

4.2 Controls

The analyzer employs a micro-processor that is controlled by two (2) pushbuttons located on the keypad on the front cover.

1. CAL initiates the calibration routine.
2. ON/OFF sends power to the electronics

4.3 Start-Up Test

Pressing the ON/OFF key, above right, not only supplies power to the electronics but initiates diagnostic tests of the electronics and battery voltage.

Low battery voltage detected during the Start -Up Test or normal operation causes the LCD display to alternate between LO and the oxygen value in the SAMPLING mode.

The sensor's signal output must be confirmed by calibrating the device as described in the following section.

4.4 Calibration

Electrochemical oxygen sensors generate slightly different signal outputs under identical conditions due to variations in the thickness of the sensing membrane and manufacturing process.

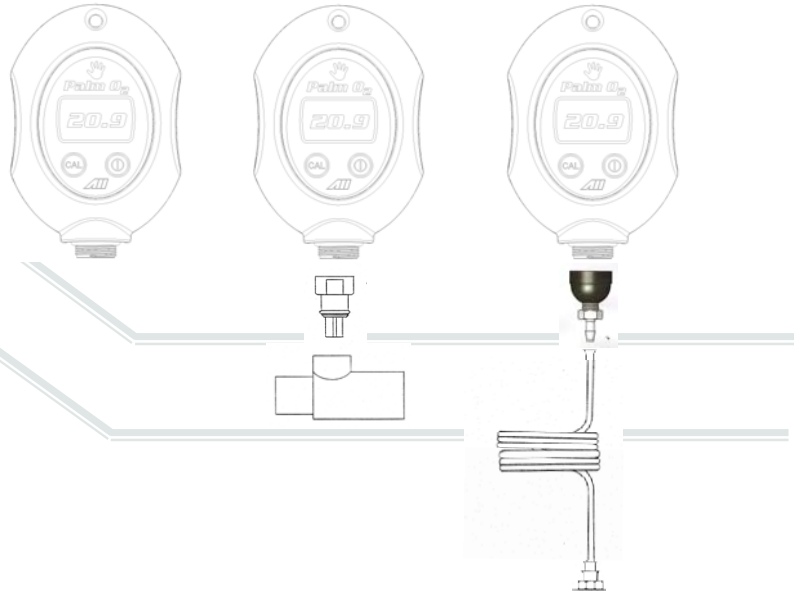
Simulate the application for optimum accuracy: Review Sections 3 Safety Warnings and 5.2 Application Considerations before proceeding.

The devices are designed to meet the requirements for both ambient and elevated oxygen measurements but should **NEVER** be calibrated with air or 21% oxygen with the intent of taking oxygen measurements at oxygen levels above 30% oxygen.

Accordingly, the devices may be calibrated with either air (20.9%) or 100% oxygen which requires the user to make a conscious decision to bypass or skip the recommended 100% oxygen calibration.

Set-Up:

Static Atmosphere | Flowing Gas Stream | Flowing from Tank



Procedure

Calibrate: (a) with a known source of dry 100% or 21% oxygen before using each day or after 8 hours of continuous use; (b) when the temperature or pressure of the operating environment changes; (c) if the oxygen sensor has been disconnected and reconnected; (d) after the battery or oxygen sensor has been replaced.

1. Expose the sensor to the calibration gas (refer to preceding section) for approximately 30 seconds to allow the sensor to stabilize.
2. Continue exposing the sensor to the calibration gas until the calibration routine is complete.
3. Press and hold the CAL pushbutton for three (3) seconds to initiate the calibration routine.
4. The LCD displays CAL, top right, during the calibration routine which takes 15-20 seconds.
5. The software determines from the sensor's signal output whether the device is being calibrated with 100% or 21% oxygen.
6. If the calibration is successful, the LCD will display, middle and bottom right, the oxygen value of the calibration gas and returns to the SAMPLING mode.
7. Remove the calibration gas and begin sampling.

Calibration Fails

If the calibration fails, the LCD will display ERR as illustrated.

An unsuccessful calibration can be caused by several problems with the sensor, calibration gas or electronics. Dropping the device will damage the sensor and electronics.

Do not proceed until corrective action is taken and the device is calibrated successfully.

If after three (3) unsuccessful attempts to calibrate: review section 7 for possible causes and corrective action or contact Analytical Industries Inc. at 909-392-6900.

4.5 Mounting

The device can be mounted to a 1" diameter pole or a book shelf using the optional Dovetail Mounting Kit (P/N A-3675-1) and Dovetail Female Clamp Pole/ Shelf (P/N HRWR-1075) as illustrated below.

The dovetail male bracket, top left and middle, is secured to the rear of the enclosure with one (1) screw and held in place by registration holes molded into the enclosure.

The 1" diameter dovetail female, top right, clamp pole/shelf is an optional accessory commonly found in medical applications.

The v-shaped male component simply slides into and out of the pole or shelf mounted female section.

5 Operation

5.1 Principle of Operation

The AII-2000 Palm O2 Oxygen Analyzer utilizes an electrochemical galvanic fuel cell type oxygen sensor of the type that is extensively used to measure oxygen concentrations from 0% to 100% in gas streams. Oxygen, the fuel for this electrochemical transducer, diffusing into the sensor through a gas permeable membrane reacts chemically at the sensing electrode to produce an electrical current output proportional to the oxygen concentration in the gas phase. The sensor has an absolute zero meaning that when no oxygen is present to be chemically reacted the LCD displays 00.0 oxygen.

The sensor's signal output is linear over the entire range, remains virtually constant over the specified useful life and drops off sharply at the end. The sensor itself requires no maintenance and is simply replaced at the end of its useful life like a battery. Inasmuch as the sensor is a transducer in its own right, its expected life is not affected by whether the analyzer is ON or OFF.

The relationship between the sensor's signal and changes with the oxygen concentration is both proportional and linear, thus allowing single point calibration. Other factors that can affect the signal output are described in Section 5.2 Application Considerations and Section 3 Safety Warnings which should be read before use.

Historically, the expected life of galvanic fuel type sensors has been specified as "in air (20.9% O_2) at 25°C and 760mm Hg". The actual life of any galvanic fuel type sensor is inversely affected by changes in the average oxygen concentration, temperature and pressure it is exposed to during its useful life. For example, the AII-11-75-PO2 and AII-11-75-PO2R sensors have a 32 month expected life in air (20.9% oxygen) at 25°C and ambient pressure, however, in a 100% oxygen atmosphere the expected life is 12.6 months [60mo/(100%/20.9%)].

AII-2000 Palm O2 Oxygen Analyzer is battery powered by (2) AA alkaline batteries and controlled by a state-of-the-art microprocessor. The batteries provide enough power to operate the analyzer continuously for approximately 13,000 hours. Both devices utilize a membrane type keypad for users to communicate commands to the microprocessor. The digital electronics provide features such as system diagnostics and warning indicators that enhance both safety and effectiveness. The design criteria, quality program and performance features ensure reliable and accurate oxygen measurements.

5.2 Application Considerations

Effect of Anesthetic Agents

The AII-2000 Palm O2 Oxygen Analyzer utilizes an electrochemical galvanic fuel cell type sensor, model AII-11-75-PO2, that has been characterized by its gas permeable sensing membrane that allows the gas to be analyzed to diffuse into the sensor where oxygen can be reacted. The displayed oxygen concentration of all sensors of this design decreases in the presence of anesthesia gases. EN 12598:1999/ISO 7767:1997 (E) established standards for the maximum error allowable over a given duration. The anesthetic agents listed (Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurance) were vaporized into a gas stream of 30% oxygen / 70% nitrous oxide.

Gas	Test Level	Decrease in O_2 Reading
Helium	50%, Balance O_2	0%
Nitrous Oxide	80%, Balance O_2	0%
Carbon Dioxide	10%, Balance O_2	0%
Halothane	4%	<-1.5%
Enflurane	5%	<-1.5%
Isoflurane	5%	<-1.5%
Sevoflurane	5%	<-1.5%
Desflurane	15%	<-1.5%

The errors listed were observed after a two (2) hour exposure period. The table above summarizes the performance of the AII-2000 Palm O2 electronics and AII-11-75-PO2 Oxygen Sensor. The above performances all meet or exceed the requirements established by EN 12598:1999/ISO 7767:1997 (E).

Do not operate any device in the presence of flammable anesthetic agents such as Diethal Ether or Cyclpropane.

Note: The AII-11-75-PO2 Oxygen Sensor has been specifically designed and tested to be compatible with nitrous oxide. For optimum results, mount oxygen sensor with the sensing area facing down toward the floor and be flushed or calibrated with 100% oxygen every eight (8) hours.

Effect of Temperature

All membrane clad electrochemical sensors are temperature dependent due to the expansion and contraction of the Teflon sensing membrane. As result more or less of the sample gas including oxygen to be reacted diffuses into the sensor. The oxygen sensor's electrical current signal output varies linearly with oxygen concentration. The signal also varies with changes in ambient temperature. The temperature coefficient is typically 2.54% of the signal or reading per degree C change in temperature.

The temperature dependent current signal output is compensated by using a resistor-thermistor network. With a proper resistor-thermistor network, the signal can be compensated to within ±5% of the oxygen reading over the 5-45°C temperature range. This is the worse case situation when going from one extreme of the operating temperature range to the other. The error will be eliminated when the thermistor in the temperature compensation network and the electrolyte inside the sensor reach thermal equilibrium in approximately 45-60 minutes.

Erroneous oxygen readings can result if the gases flowing over the sensing area of the sensor are not at ambient temperature. This occurs because the sensor is exposed to different temperatures. The sensing area of the sensor is o-ring sealed in the heated breathing circuit and the temperature compensation network at the rear of the sensor is exposed to ambient temperature.

Effect of Pressure

Electrochemical sensors actually measure the partial pressure, not the percentage, of oxygen in the gas stream they are exposed to. These sensors are accurate at any pressure provided the pressure is constant and the analyzer has been calibrated at the same pressure as the sample gas measured.

For example, when connected to a gas stream where the pressure varies, the oxygen sensor causes the analyzer to display fluctuating oxygen readings. The fluctuations in the readings displayed are not related to a change in the oxygen percentage but to the change in partial pressure resulting from the alternating breathing pressure cycles of a ventilator which increases the total pressure.

Calibrate at the temperature and pressure (altitude) at which the analyzer will be operated.

Effect of Humidity

The analyzer is not affected by non-condensing relative humidity (RH). However, the use of a humidifier to introduce water vapor and increase the moisture level of the gas mixture does affect the oxygen concentration and the resultant reading displayed by the analyzer. The addition of water vapor increases the total pressure thereby diluting or decreasing the oxygen concentration of the gas mixture resulting in a lower oxygen reading.

Calibrate at the temperature and pressure (altitude) at which the analyzer will be operated, humidified gases cannot be 100% oxygen.

Effect of Condensation

Excessive condensation collecting on the sensing area or the electrical connections at the rear of the sensors can adversely impact the performance of electrochemical sensors. Condensation blocks the diffusion path of oxygen into the sensor and can reduce the oxygen reading to 00.0 if the condensation covers the entire sensing area. Condensation on the electrical connections at the rear of the sensor can affect oxygen readings. Remedy either situation by shaking out the condensation and allowing the sensor to air dry.

Erroneously characterized in many instances as a sensor failure, excessive condensation is remedied by gently wiping away the condensation with a soft cloth or simply allowing the sensor to air dry.

Effect of Electromagnetic Radiation

Tested over a 26 MHz to 1000 MHz electromagnetic field, the analyzer is susceptible at all frequencies tested except those between 930 and 990 MHz.

Never operate the analyzer near equipment capable of emitting high levels of electromagnetic radiation. Do not continue to operate the analyzer if the reading becomes unstable.

5.3 Calibration

Calibrating the analyzer during normal operation involves the same precautions and procedures as those described in Sections 4.4 Start-up Calibration with the same cautions to review Sections 3 Safety Warnings and 5.2 Application Considerations.

5.4 Sampling

Assuming the START-UP TESTS are completed successfully the devices default to the SAMPLING mode.

Never operate the analyzer if the reading is unstable or if a malfunction is suspected. If calibration is required as indicated herein, do not proceed until the analyzer is calibration successfully.

5.4.1 Flowing Gas Streams (Breathing Circuits, Concentrators)

1. Place the sensing area of the sensor into the gas stream to be analyzed upstream of any humidification equipment.
2. Assure that the flow rate of the gas stream does not exceed ten (10) liters per minute. Exceeding ten (10) liters per minute generates backpressure.
3. Check the gas stream and particularly the mechanical connection for leaks that dilute the gas stream with ambient air.
4. Assure there are no restrictions in the circuit downstream of the sensor that could generate backpressure on the sensor.
5. Use the flow diverter supplied with the device along with the optional tee adapter and position the sensor vertically for optimum results, as shown right. The flow diverter avoids stagnation and facilitates the movement of gas to and from the sensing area of the sensor thereby producing a more accurate measurement of the gas stream to be measured.
6. Install the tee-adapter in the breathing circuit.
7. Screw the flow diverter to the sensor.
8. Ensure the o-ring is lightly lubricated for ease of entry and a tight seal between the flow diverter and tee adapter.
9. Insert the assembled flow diverter/sensor into the tee allowing 100% oxygen (dry, non-humidified) to flow past the sensor at a rate of 5-8 liters per minute.
10. Once the sensing area of the sensor is exposed to the gas stream allow approximately sixty (60) seconds for the reading to stabilize and observe the reading displayed by the LCD.

Flowing Gas Stream

Flowing from Tank

5.4.2 Static Atmospheres (Incubators, Hoods, Oxygen Tents)

Expose the sensing area of the sensor to the atmosphere allowing approximately sixty (60) seconds for the reading to stabilize and observe the reading displayed by the LCD.

If placing the entire sensor inside the controlled atmosphere review Section 5.2

Static Atmosphere

6 Maintenance

Review Section 3 Safety Warnings and Section 7 Troubleshooting for guidelines on servicing the devices.

6.1 Serviceability

Do not open the main compartment of the analyzer, as it contains no serviceable parts inside. Never attempt to repair the analyzer or sensor by yourself as you may damage the analyzer which could void the warranty.

6.1.2 Cleaning / Reuse Instructions

Clean the device, oxygen sensor and accessories with a soft cloth dampened with either water or mild isopropyl alcohol solution (70% isopropyl alcohol solution in water), if necessary, before re-use. Allow the components to air-dry after cleaning.

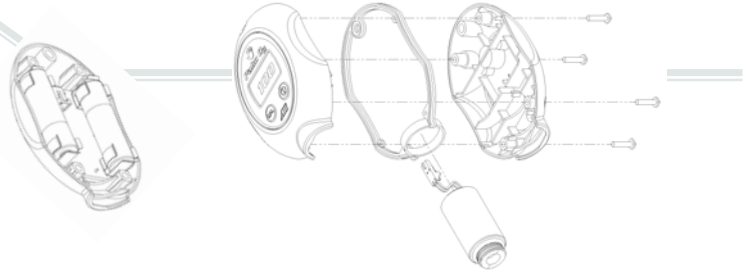
Note: The Home Care Kit is not intended for patient use, it is intended solely for confirming the O_2 concentration in Oxygen Concentrators. Accordingly, no cleaning instructions apply.

6.2 Battery Replacement

The AII-2000 Palm O2 Oxygen Analyzer is powered by two 1.5V AA alkaline batteries with an approximate life of 13,000 hours.

A low battery indicator circuit monitors the battery supply voltage and sends a signal directly to the LCD when the battery voltage reaches a preset level that activates the battery symbol in the LCD.

The batteries are located the top or front of the analyzer and secured by terminals mounted directly on the PCB Assembly.



Procedure:

1. Open the enclosure: Remove the four (4) Phillips screws from the rear of the enclosure, FIG 1.
2. Separate the enclosure and an place it on a flat surface, FIG 2.
3. Remove the battery: Grasp the middle of a battery and gently pull straight up.
4. Locate the positive (+) and negative (-) terminals on the battery.
5. Assure the battery contacts are clean.
6. Align the battery's positive (+) terminal with the corresponding (+) battery symbol printed on the PCB Assembly.
7. Install the battery: Align the battery over the terminal clip mounted on the PCB Assembly and press down until the battery snaps into place, FIG 2.
8. Repeat steps 3-7 with the remaining battery.
9. Reassemble the device as shown in section 6.4
10. Calibrate, see section 4.4, the device after replacing the batteries.

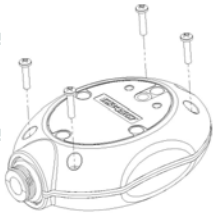


FIG 1

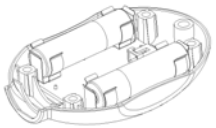


FIG 2

6.3 Oxygen Sensor Replacement - Standard Integral Sensor

The design of the electronics is intended for only the Analytical Industries Inc. AII-11-75-PO2 or AII-11-75-PO2R Oxygen Sensors. Use of a different oxygen sensor may result in an erroneous oxygen reading.

NEVER - Open the oxygen sensor or probe the sensing surface, refer to Section 10 in the event the sensor should leak and someone comes in contact with the electrolyte from inside the sensor.

Procedure - Standard Integral Sensor

1. See 6.2 step 1 above.
2. See 6.2 step 2 above.
3. Disconnect the oxygen sensor: Press down on the latch arm, see arrow, and pull back on the male connector attached to the sensor from the female connector attached to the PCB Assembly, FIG 3.

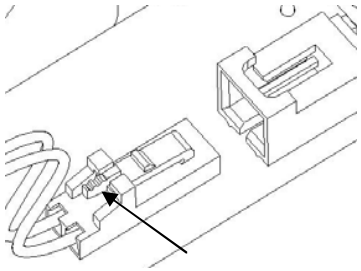


FIG 3

4. Remove the oxygen sensor, FIG 4:
   (a) Lift up the rear of the sensor where the connector wires are attached.
   (b) Pull the front end of the sensor out of the retaining collar, arrow right, molded into the gasket that seals the two sections of the enclosure.
5. Install the new oxygen sensor:
   (a) Align the rear of the sensor as shown in FIG 5, but do not install.
   (b) Insert the sensor into the molded collar, arrow FIG 6, and align the outer shoulder with the front edge of the collar.
   (c) Locate the registration peg indicated by the arrow circled in FIG 5.
   (d) Gently press the hole where the wires exit the sensor onto the registration peg, FIG 5.

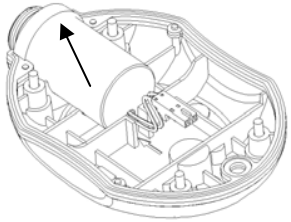


FIG 4

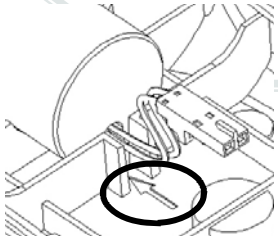


FIG 5

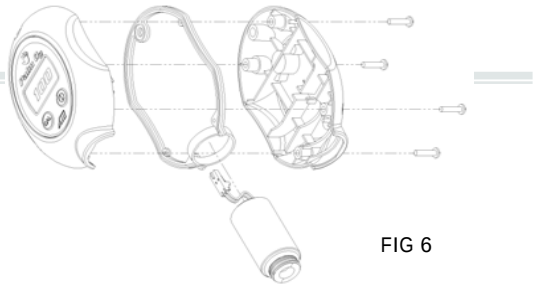


FIG 6

6. Connect the sensor, reverse section step 3.
7. Reassemble the device as shown in section 6.4.
8. Calibrate, see section 4.4, the device after replacing the sensor.

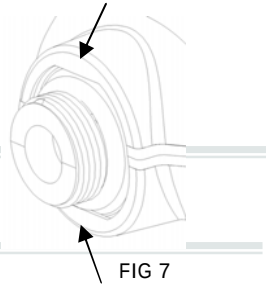


FIG 7

6.4 Reassembly

To ensure proper operation after replacing the sensor or batteries check the following points:

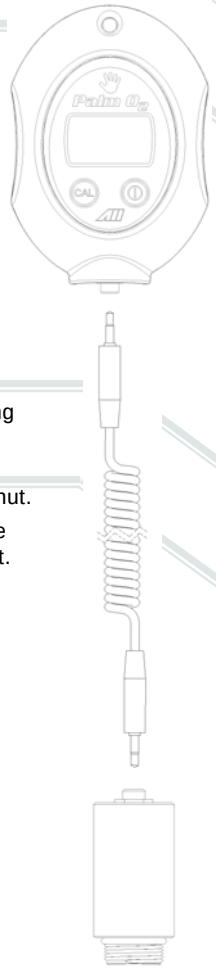
1. The batteries are secured in the terminal clip.
2. The sealing gasket is registered onto the 4 pegs molded into the bottom section of the enclosure.
3. The sensor is registered as shown in FIG 5 and FIG 7 and the connecting wires are not bent or bound when closing up the enclosure and tightening the Phillips screws, FIG 6.

6.5 Oxygen Sensor Replacement - Optional Remote Sensor

The design of the electronics is intended for only the Analytical Industries Inc. AII-11-75-PO2 or AII-11-75-PO2R Oxygen Sensors. Use of a different oxygen sensor may result in an erroneous oxygen reading.

NEVER - Open the oxygen sensor or probe the sensing surface, refer to Section 10 in the event the sensor should leak and someone comes in contact with the electrolyte from inside the sensor.

With this configuration the integral oxygen sensor is replaced by a connector module (P/N A-3654). The external oxygen sensor (P/N AII-11-75-PO2R) is connected to the module by a cable (P/N CABL-1009) with phone plug and locking nut attached at both ends. The cable is coiled and extends to 6 ft.



Procedure - Optional Remote Sensor

1. Unscrew the locking nut from the connector located at the rear of the oxygen sensor.
2. Remove the new replacement sensor from its shipping packaging.
3. Insert the phone plug into the connector at the rear of the oxygen sensor and finger tighten the locking nut.
4. Allow the new replacement oxygen sensor to stabilize for approximately 30 minutes in its new environment.
5. Calibrate, see section 4.4, after replacing the remote oxygen sensor.

7 Troubleshooting

If the recommended corrective action does not resolve the problem return the device to the factory for service.

Symptom	Corrective Action
Device appears to be physically damaged	Turn device ON – if it successful passes calibration – proceed
No display when analyzer is turned ON	Replace batteries Check battery polarity Check and/or clean battery contacts
'LO' displayed when analyzer is turned ON or in use.	Replace battery and calibrate device
'ERR' displayed when analyzer fails calibration	Replace oxygen sensor
No response to keypad	Replace battery
Cannot turn device OFF	Calibration routine in process – wait until completed
Reading displayed by LCD does not change when oxygen level changes	Replace sensor
After calibration in 100% dry oxygen, analyzer reading drifts more than 2% over 8 hours	Check primary oxygen delivery device Replace sensor that is nearing the end of its useful life
Reading does not stabilize or fluctuates erratically	Relocate analyzer away source of RF or electromagnetic radiation emissions. Wait 5 minutes and repeat calibration Replace sensor, repeat calibration

8 Specifications

Accuracy:	< 2% of FS range under constant conditions
Analysis:	0-100% oxygen
Alarms:	Analyzer none
Calibration:	Certified dry 100% oxygen or air after 8 hrs of use
Compensation:	Temperature
Connections:	1x16mm thread or o-ring diverter
Controls:	Soft touch keypad for ON/OFF and CAL
Dimensions:	2.72" x 4.1" x 1.35"; weight 7 oz. (196 grams)
Display:	3 digit LCD 1.1" x .625"; resolution 0.1% O_2
Flow Sensitivity:	None between 0.2 to 10 liters per minute
Humidity:	Non-condensing 0-95% RH
Linearity:	± 1% under constant conditions
Pressure:	Inlet – ambient or regulated; vent - atmospheric
Power:	(2) 1.5V AA alkaline batteries; 13,000 hrs of use
Response Time:	90% of final FS reading in 10 seconds
Sensitivity:	< 0.5% of FS range
Sensor:	AII-11-75-PO2; optional remote sensor AII-11-75-PO2R
Sensor Life:	32 months in air at 25ºC and 1 atmosphere
Storage Temp.:	-20º to 60ºC (-4ºF to 140ºF) on intermittent basis
Temp. Range:	5º to 45ºC (41ºF to 113ºF)
Warm-up Time:	None
Warranty:	12 months analyzer; 12 months sensor (any application)

8.1 Spare Parts & Optional Accessories

Spare Parts:

AII-11-75-PO2 Oxygen Sensor

BATT-1008 Battery (2x) 1.5V AA Alkaline

P-1087 Instructions for Use

A-1162 PCB Assy Main

FITN-1112-1 Flow Diverter, O-ring Seal

Optional Accessories:

Remote Oxygen Sensor Kit

AII-2000 Palm O2 with A-3654 Remote Sensor Connector

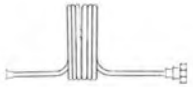
CABL-1009 Cable 6 ft. Phone Plug with Lock Nut

AII-11-75-PO2R Oxygen Sensor

A-3675-1 Home Care Kit

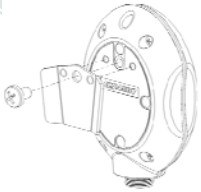
AII-2000 Palm

A-3675 Adapter 5/32" Tube to Sensor



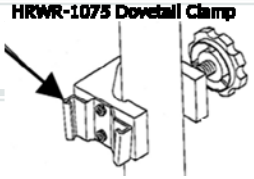
TUBE-1007 Tubing, 1/4" 7 ft. with Adapter

A-3657-1 Dovetail Mounting Kit

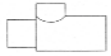


A-3657 Dovetail Bracket
HRWR-1162 Screw 1/4-20 x 3/8"

HRWR-1075 Dovetail Clamp



FITN-1009 Tee Adapter



HRWR-1157 Screwdriver

HRWR-1158 Lanyard

9 Warranty

Coverage
Under normal operating conditions, the analyzer and sensors are warranted to be free of defects in materials and workmanship for the period specified in the current published specifications. To make a warranty claim, you must return the item properly packaged and postage prepaid to:

Analytical Industries Inc.
2855 Metropolitan Place
Pomona, Ca 91767 USA
T: 909-392-6900, F: 909-392-3665
E: sales-medical@aii1.com, W: www.aii1.com

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. If we choose to repair your item, we may use new or reconditioned replacement parts of the same or upgraded design. 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 begins with the date of shipment from Analytical Industries and is limited to the first customer who submits a claim for a given serial number which must be in place and readable to be eligible for warranty and will not extend to more than one customer or beyond the warranty period under any conditions.

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 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.

Service
Contact us between 8:00am and 5:00pm PST Monday thru Thursday or before 12:00pm on Friday. Trained technicians will assist you in diagnosing the problem and determining the appropriate course of action.

10 Material Safety Data Sheet (MSDS)

Product name	Electrochemical Galvanic Fuel Cell Oxygen Sensor
Exposure	Sealed device with protective coverings, normally no hazard
Ingredients	Carcinogens - none; Potassium Hydroxide (KOH), Lead (Pb)
Properties	Completely soluble in H_2O; evaporation similar to H_2O
Flash Points	Not applicable, non-flammable
Reactivity	Stable; avoid strong acids, emits fumes when heated
Health Hazard	KOH entry via ingestion - harmful or fatal if swallowed; eye - corrosive, possible loss of vision; skin contact - corrosive, possible chemical burn. Liquid inhalation is unlikely. Lead - known to cause birth defects, contact unlikely
Symptoms	Eye contact - burning sensation; skin contact - slick feeling
Protection	Ventilation - none; eye - safety glasses; hands - gloves
Precautions	Do not remove Teflon and PCB coverings; do not probe with sharp objects; avoid contact with eyes, skin and clothing.
Action KOH Leak	Use rubber gloves, safety glasses and H_2O and flush all surfaces repeatedly with liberal amounts of H_2O

10.1 Disposal
Oxygen sensors and batteries should be disposed of in accordance with local regulations for batteries.

WEEE regulations prohibit electronic products including the Helium and environmental sensors from being placed in household trash bins.

Electronic products should be disposed of in accordance with local regulations.