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

Medical Device Directive: 93/42 EEC, Annex II
EN ISO 13485:2016, MDSAP

**0123** EN ISO 80601-2-55:2011, Part 2-55
Particular requirements to the basic safety and essential performance of respiratory gas monitors

EN ISO 14971:2012
Application of risk management to medical devices

ISO 9001:2015

Authorized EC Representative:
Distribuciones Y Representaciones Biomedicas Direx, S.L.
Avda. San Pablo, 28. Nave 24,
2882 Coslada Madrid, Espana

Health Canada: Medical Devise Regulations, F-27/ SOR-98-282
ISO 13485:2016

**P-1087 Instructions for Use**

**Effective 12/19**
**Revised: December 20, 2019**

Analytical Industries Inc.,
2855 Metropolitan, Pomona, CA 91767 USA.
Tel: 909-392-6900, Fax: 909-392-3665
e-mail: sales-medical@aii1.com, web: www.aii1.com



Analytical Industries Inc.

# Instructions for Use

# AII-2000 Series
## O2 Analyzers & Monitor


AII-2000 A


AII-2000 HC


AII-2000 M

# 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 Series Oxygen Analyzers & Monitor.

⚠ 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 Series Oxygen Analyzers & Monitor are 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 12 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.

### 1.2 Intended Use

The oxygen sensor as an accessory of either the AII-2000 Series Oxygen Analyzers & Monitor or other OEM device is intended for short term use to monitor and display an independent secondary confirmation of the oxygen concentration in breathing gas mixtures administered in combination with therapeutic devices such as lung ventilators and incubators; monitoring vital physiological processes and parameters such as respiration, anaesthesia, intensive or emergency care; monitoring the administration of gases using ventilators, anaesthesia machines, hyperbaric chambers and medical gas mixers.



### 1.3 Device Description

The AII 2000 Series Oxygen Analyzers and Monitor 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 devices utilize 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 features like system diagnostics, warning indicators, controls and an alarm capability for continuous monitoring that enhance both safety and effectiveness.

Prior to shipment, every device is thoroughly tested at the factory and documented by the Quality Control & Calibration Certification in section 13 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 13 Quality Control Certification.

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

# 2 General Safety

**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's sensing surface is dry; and, (c) the sensor is installed upstream from any humidifying device for accurate calibration and oxygen measurements.
- 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 changes more than ±10°C from calibration temperature; (c) when the pressure of the operating environment changes; (d) if the oxygen sensor has been disconnected and reconnected; (e) after the battery or oxygen sensor has been replace.
- Sampling flowing gas: (a) install the flow diverter and the tee-adapter in a vertical position as shown in Section 5.3 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 this re-usable device and accessories in accordance with Section 6.1.2., particularly if it comes in contact with the patient's bodily fluids in which case consider disposing of the device depending on extent.
- 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 guide in section 8 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 or users.

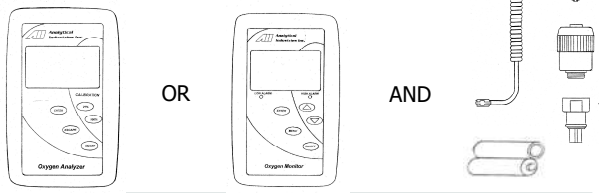
- In the event of a failure during the START-UP TESTS which cannot be resolved by a restart that passes all START-UP TESTS and calibration.
- After the battery symbol appears in the LCD display.
- Near equipment capable of emitting electromagnetic radiation (EMI) or radio frequency interference (RFI), e.g. near X-ray and MRI machines.
- Without first discharging static electricity (ESD) from yourself.
- 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 11, for extended periods of time.
- If the reading becomes unstable or a malfunction is suspected. Consult the Troubleshooting guide in section 8. If in doubt, contact the manufacturer for assistance.
- In the presence of flammable anesthetic gases.
- 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 11 - 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 40% 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, or immerse in any liquid or expose the device or accessories to steam, ethylene oxide or radiation sterilization.
- Open the main compartment of the device, except to change the integral oxygen sensor of the AII-2000 HC Oxygen Analyzer.
- 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.
- Operate 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.

# 3 Start-Up

**3.1 Contents of Shipping Container:**

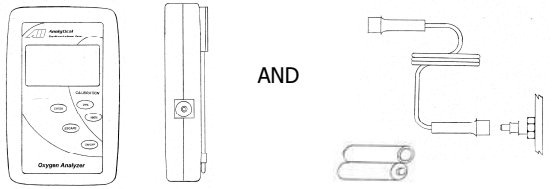
**3.1.1 AII 2000 A Oxygen Analyzer, and AII 2000 M Oxygen Monitor:**

ENCL-1061 V-mount retainer (attached)
ENCL-1066 Tripod wire stand (attached)
AII-11-60 Oxygen Sensor
BATT-1008 Battery, AA 1.5V Alkaline (Qty 2)
CABL-1006 Cable, Coiled Phone Jack
FITN-1009 Blue Tee Adapter
FITN-1112-1 Flow Diverter
P-1087 Instructions for Use




**3.1.1 AII 2000 HC Oxygen Analyzer, Home Care:**

ENCL-1061 V-mount retainer (attached)
ENCL-1066 Tripod wire stand (attached)
AII-11-60-HC Oxygen Sensor (installed inside analyzer)
BATT-1008 Battery, AA 1.5V Alkaline (Qty 2)
TUBE-1007 Tubing, 1/4" Tubing 7 ft. with Adapter
P-1087 Instructions for Use



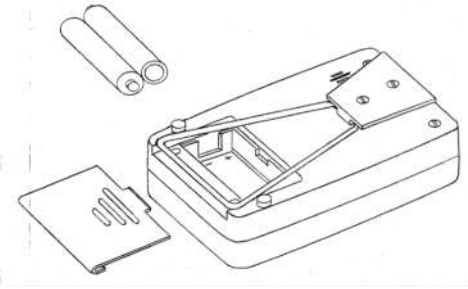

Inspect the box and contents for shipping damage. If the device or components appear damaged, do not attempt to operate the device - contact the manufacturer immediately, refer to section 9.



**3.2 Install Batteries**

All devices are powered by two 1.5V AA alkaline batteries which must be installed before the device can be operated.

The battery compartment is located at the rear of all devices. Initially this procedure can be somewhat difficult. Care should be taken not to damage the case when removing the battery compartment cover.



**3.2.1 Procedure:**

1. Remove the device and the (2) AA 1.5V Alkaline batteries from the foam shipping container.
2. Turn the device over so the shortest raised line on the battery compartment cover is pointing away from you.
3. Lift the tripod wire stand up and away from the case.
4. Grasp the case with both hands, use your thumbs press down firmly on the raised lines and push the battery compartment cover away from you.
5. Locate the positive (+) and negative (-) terminals on the battery.
6. Assure the battery contacts are clean.
7. Align one battery's positive (+) terminal with the corresponding (+) battery symbol molded into the case.
8. Insert the battery into the compartment.
9. Repeat with the remaining battery.
10. Replace the battery compartment cover, make sure it snaps into position and is secured flush against the case. Replace the wire stand as required.

Replace the batteries within twenty-four (24) hours of the battery symbol appearing on LCD display because batteries decline at different rates. Calibrate the device after replacing the batteries.

### 3.3 Install Oxygen Sensor

The device cannot function until the oxygen sensor is installed. Once installed, allow the sensor to stabilize for 15-20 minutes in ambient air before attempting to calibrate the device.

**NEVER - Attempt to open, repair or service the oxygen sensor.** Refer to section 2 for hints and warnings concerning the handling and environmental considerations of the oxygen sensor and the device.

#### 3.3.1 AII 2000 A Oxygen Analyzer, AII-2000 M Oxygen Monitor:

1. Remove the contents from the shipping container as shown in section 3.1 and check for damage.
2. The coiled cable uses a common RJ11 phone jack at both ends, making a bad connection impossible.
3. Install the sensor away from any humidifying device to prevent moisture from condensing on the sensing surface and assure accurate calibration and oxygen readings.
4. Connect one end of the cable to the device in the same manner you would connect a telephone. Simply find and register the male plug at the end of the coiled cable and insert it into the mating female jack on the side of the device.
5. Connect the other end of the cable to the sensor in the same manner.
6. For diffusion sampling of static, ambient or controlled atmospheres – incubators, infant hoods, tents, etc., the flow diverter and tee are not required as shown above.
7. For sampling breathing circuits with flowing gas, use the flow diverter and tee adapter accessories supplied with the device, 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.
8. Install the tee-adapter in the breathing circuit.
9. Screw the flow diverter to the sensor.
10. Ensure the o-ring is lightly lubricated for ease of entry and a tight seal between the flow diverter and tee adapter.
11. Insert the assembled flow diverter/sensor into the tee allowing 100% oxygen (dry, non-humidified) to flow past the sensor at a rate less than 10 liters per minute.

#### 3.3.2 AII 2000 HC Oxygen Analyzer:

When the Home Care version with its integral oxygen sensor is ordered, the device is shipped with the sensor installed.



### 3.4 Controls

#### 3.4.1 AII 2000 A and AII 2000 HC Oxygen Analyzers

These analyzers employ a micro-processor that is controlled by five (5) pushbuttons located on the keypad attached to front cover.

1. ON/OFF provides power to the electronics
2. ESCAPE aborts a previous selected option
3. ENTER selects a menu option
4. 100% initiates the routine for CALIBRATION with 100% oxygen. The sensor must be exposed to 100% oxygen.
5. 21% initiates the routine for CALIBRATION with air or 21% oxygen. The sensor must be exposed to air or 21% oxygen.

#### 3.4.2 AII 2000 M Oxygen Monitor

The monitor employs a menu driven micro-processor that is controlled by five (5) pushbuttons located on the keypad attached to front cover.

1. ON/OFF provides power to the electronics
2. MENU accesses the MAIN MENU
3. ENTER selects a menu option, and, enables the user to silence the audible alarm quickly without having to navigate through the menu(s)
4. DOWN ARROW scrolls down the menu options
5. UP ARROW scrolls up the menu options

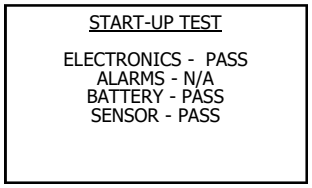
**Note:** The monitor is equipped with visual and audible HIGH and LOW (minimum set point of 15%) alarms which are controlled through the MAIN MENU and are activated when the oxygen value is 0.1% below the LO alarm set point or 0.1% above the HI alarm set point, refer to section 3.6 below.

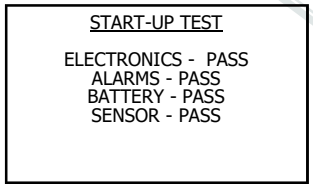
#### 3.4.3 Instructions and Warnings displayed by LCD

- START-UP TEST – diagnostic tests of the electronics, alarm circuit (monitors only), battery voltage and the sensor's signal output.
- SERVICE DEVICE – non-sensor failures during the start-up test.
- CHECK SAMPLE GAS, CHECK CABLE, CHECK SENSOR – sensor fails the start-up test or becomes disconnected during operation, or if an alarms is activated (monitor).
- SAMPLING – oxygen concentration from 0-100% in the sample gas during the normal operation.
- BAT LOW – battery voltage is not adequate, replace batteries.
- ALARM SET POINTS, CONDITION (set point reverses color and red LED indicator turns on) for monitor only.

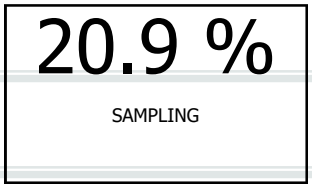
### 3.5 Start-Up Test

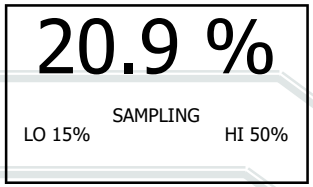
Press the ON/OFF key on the front panel to apply power to the device and initiate a complete diagnostic test of all system functions: the electronics, feeds voltage and tests the alarm circuit (monitor only below right) internally, confirms the battery voltage is adequate to power the circuit, and, the sensor's signal output is within specifications.




Following successful Start-Up Test the devices default to the SAMPLING mode.



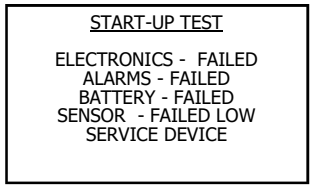




With the exception of the ALARMS for the AII-2000 M (above right) the tests and resulting displays are the same.

**Note:** Any START-UP TEST failure requires the user to take corrective action before continuing or attempting to use any device.

#### 3.5.1 Electronics, Alarms (AII-2000 M Monitor) or Battery Failure

If any of these START-UP TESTs are unsuccessful, the following display instructs the user to SERVICE DEVICE. The following display is the same for all models.





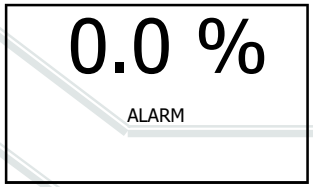

#### 3.5.2 Sensor Failure

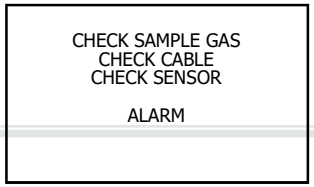
Sensor failure can result from multiple causes; the user's failure to connect a sensor or sensor cable, a defective sensor cable or a sensor with an output outside specification.

SENSOR - FAILED LOW is one of the possible unsuccessful START-UP TESTs as illustrated previously and displays additional warnings as follows.

#### 3.5.2.1 AII 2000 A and AII 2000 HC Oxygen Analyzers

The LCD alternately displays the following until the problem is corrected.

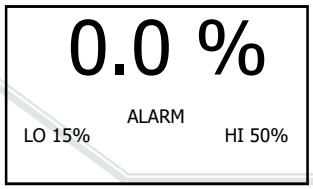


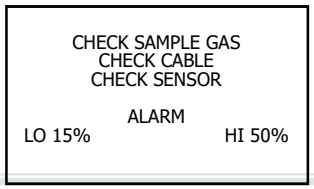




Corrective action:
1. Expose the sensor to air or a gas containing approximately 20.9% oxygen
2. Connect or replace the cable connecting the sensor to the analyzer
3. Connect or replace the oxygen sensor

#### 3.5.2.2 AII 2000 M Oxygen Monitor

Performs the same routine and requires the same corrective action as the analyzers above with additional indicators related to the monitor's alarm feature.




In addition to the alternating LCD display, the LO ALARM becomes active and:

- LO ALARM value and background alternately reverse colors on the LCD
- RED LED below the LO ALARM value lights up and begins flashing
- Audible alarm begins beeping

The audible alarm can be disabled for two (2) minutes (unlimited times) by:
1. Press the MENU key on the front panel
2. Press the UP/DOWN arrow to select ALARMS AUDIBLE
3. Press the ENTER key to toggle to ALARMS SILENT mode

### 3.6 Alarms AII 2000M Oxygen Monitor

The monitor is equipped with user selectable HI and LO alarm set points which are displayed at the bottom of the LCD. The default alarm set points are 15% LO and 50% HI. The LO alarm set point can be set between 15% and 99% and the HI alarm set point can be set between 16% and 100%.

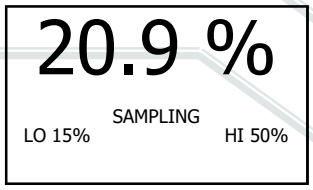
Alarm set points may be adjusted in 1% increments by pressing and holding the UP/ DOWN ARROW keys, see below. The ARROW keys are disabled when the alarm set points are within 1% of each other to prevent the HI alarm from being set below the LO alarm. The HI alarm may be disabled by attempting to select a HI alarm set point above 100% to facilitate flushing patients after anesthesia. In this mode the LCD continually displays HI OFF.

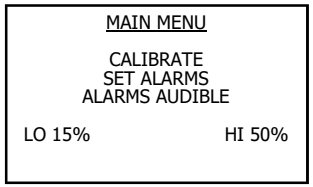
The AII-2000 M Oxygen Monitor is equipped with four (4) indicators that activate when oxygen concentrations are 0.1% below the LO alarm set point or 0.1% above the HI alarm set point.

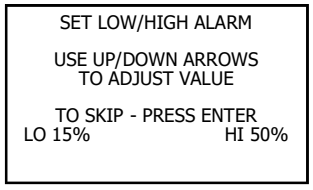
1. LCD alternates between the ALARM mode with an oxygen reading 0.0% and recommendation as illustrated in sections 3.5.2.1 and 3.5.2.2
2. Alarm value and background alternately reverse color on LCD
3. Red LED below the alarm value lights up and begins flashing
4. Audible alarm begins beeping

#### 3.6.1 Setting Alarm Set Points

1. From the SAMPLING mode press MENU to display the MAIN MENU
2. Press the UP/DOWN arrow keys to highlight SET ALARMS
3. Press ENTER to select SET ALARMS
4. LO alarm value is highlighted by default
5. Press ENTER to skip the LO alarm (and proceed to the HI alarm) or press the UP/DOWN arrow keys to change the alarm set point
6. Press ENTER to save LO alarm set point and move to select the HI alarm
7. Press ENTER to skip the HI alarm (and return to SAMPLING mode) or press the UP/DOWN arrow keys to change the alarm set point
8. Press ENTER to save HI alarm set point and return to SAMPLING mode
9. If no key is pressed within 5 seconds, the LCD returns to the SAMPLING mode





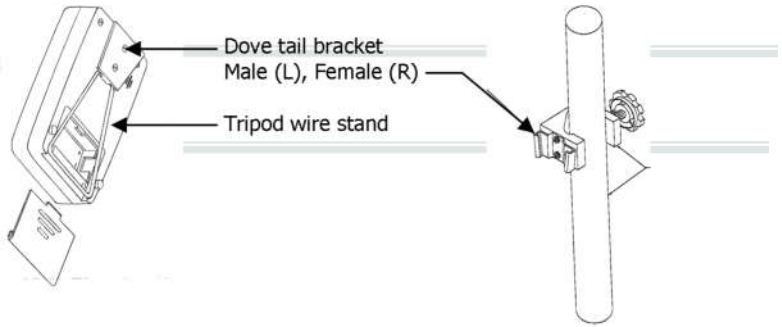

### 3.7 Mounting

Every analyzer and monitor is equipped with a male dove tail bracket and triangular shaped thick metal wire stand secured to the rear of the enclosure.

**Tripod Wire Stand**

Secured between bumper feet on either side of the battery compartment is a triangular shaped thick metal wire stand that is hinged under the dove tail bracket secured at the opposite end of enclosure.

Unsnap the triangular thick metal wire stand from between the bumper feet and pull it away from the enclosure to form a tripod which allows the device to sit upright on any flat surface




**Dove Tail Bracket**

The male dove tail bracket is secured to the rear of the enclosure with two screws. The 1" female dove tail pole bracket (HRWR-1075) is an optional accessory that is commonly found in medical applications. The v-shaped male component simply slides into and out of the pole mounted female section.

# 4 Calibration

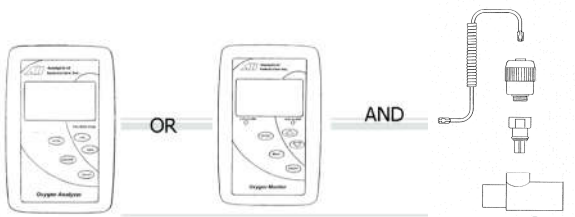
Electrochemical oxygen sensors generate slightly different signal outputs under identical conditions due to variations in the thickness of the sensing membrane and manufacturing process.

Simulate the application for optimum accuracy: Review Sections 2 General Safety and 5.2 Application Considerations before proceeding.

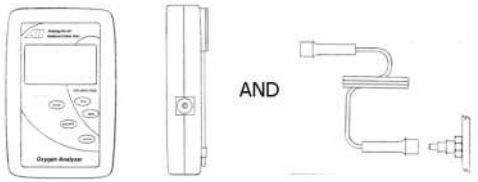
The devices are designed to meet the requirements for both ambient and elevated oxygen measurements but should **NEVER** be calibrated with air or 21% oxygen with the intent of taking oxygen measurements at oxygen levels above 30% oxygen.

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:**




AII-2000 A and AII-2000 M refer to sections:
5.4.1 Flowing Gas Streams or
5.4.2 Static Atmospheres.




AII-2000 HC refer to section 5.4.3.



**Procedure**
AII 2000 Series Analyzers and Monitor employ the identical calibration routine and displays but they differ slightly in the way they arrive at the display that initiates calibration routine. Refer to Set-Up illustration and references above for gas connections.

1. AII-2000 A and AII-2000 HC Oxygen Analyzers - Press the 21% key under the word CALIBRATION on the front panel.

1a. AII-2000 M Oxygen Monitor - Requires navigating its menu to reach the display that initiates the calibration routine.
   a. From the SAMPLING menu, press MENU to display the MAIN MENU
   b. Press the UP/DOWN arrow keys to highlight CALIBRATE
   c. Press ENTER to select CALIBRATE (the four (4) alarm indicators are disabled during the calibration routine)

MAIN MENU

CALIBRATE
SET ALARMS
ALARMS AUDIBLE

LO 15% HI 50%

2. Both of the above produce the following display which initiates the calibration routine.

20.9 %
INTRODUCE AIR/21% OXYGEN
OBSERVE TREND
PRESS ENTER TO CAL

3. The above prompt remains on the display until:
   a. The operator presses ENTER to proceed or
   b. The ESCAPE key on the AII-2000 A and AII-2000 HC or the MENU key on the AII-2000 M to abort and return to the SAMPLING mode.
4. Expose the sensor to a known source of fresh ambient air or certified 21% (dry, non-humidified) oxygen nitrogen mix but not the oxygen enriched room air commonly found in hospitals.
5. Once a suitable calibration gas is introduced, press ENTER to initiate calibration as displayed right and disable the key pad (to prevent the calibration routine from being interrupted).
6. This display appears for sixty (60) seconds to allow the sensor to stabilize before the microprocessor takes the final reading.

20.9 %
AIR CALIBRATION
IN PROCESS

7. If the calibration is successful, the display below left appears for three (3) seconds before defaulting to the display below right:

| | |
|---|---|
| 20.9 %<br>AIR CALIBRATION<br>SUCCESSFUL | TO SKIP 100% O2 CAL<br>PRESS ENTER<br><br>FOR 100% O2 CAL<br>WAIT FOR NEXT<br>DISPLAY |

8. The display above right requires a decision by the user (refer to warnings at the beginning of this section) to press ENTER and skip the 100% O2 calibration and return to the SAMPLING mode; or, wait ten (10) seconds for the following display:

20.9 %
INTRODUCE 100% O2
OBSERVE TREND
PRESS ENTER TO CAL

9. Repeat steps #3 through #6 using a certified source of 100% oxygen.

10. If the calibration is successful, the display at right appears for five (5) seconds before defaulting to the SAMPLING mode.

100 %
OXYGEN CALIBRATION
SUCCESSFUL

**Calibration Fails**
An unsuccessful calibration can be caused by several problems as displayed at right:

If after three (3) unsuccessful attempts to calibrate: review section 8 for possible causes and corrective action or contact Analytical Industries Inc. at 909-392-6900.

AIR / 100% O2 CALIBRATION
FAILED

- CHECK CAL GAS
- CHECK CABLE
- CHECK SENSOR

RETRY - PRESS ENTER

To abort the RETRY press ESCAPE (analyzer) or MENU (monitor). Do not proceed until the analyzer is calibration successfully.



# 5 Operation

**5.1 Principle of Operation**
The AII 2000 Series Oxygen Analyzers and Monitor utilize 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-11-60 sensor has a 60 months 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 Series Oxygen Analyzers and Monitors are 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 1,200 hours. Both devices utilize a membrane type keypad for users to communicate commands to the microprocessor. The monitor is menu driven to accommodate the alarm functions. The digital electronics provide features such as system diagnostics, warning indicators, controls and an alarm capability for continuous monitoring 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 Series Oxygen Analyzers and Monitors utilize an electrochemical galvanic fuel cell type sensor, model AII-11-60, 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 ISO 80601-2-55:2011 established standards for the maximum error allowable over a given duration. The anesthetic agents listed (Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane) 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 Series electronics and AII-11-60 Oxygen Sensor which all meet or exceed the requirements established by EN ISO 80601-2-55:2011.

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

**Note:** The AII-11-60 Oxygen Sensor has been specifically designed and tested to be compatible with nitrous oxide. For optimum results, mount the 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 $\pm$5% of the oxygen reading over the 5-45°C operating 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 ventilator circuit, the six (6) second T90 response time of the AII-11-60 Oxygen Sensor causes the analyzer to display an increase in the oxygen reading displayed when in fact the alternating breathing pressure cycles generated by the ventilator is increasing the total pressure. The increase in the reading displayed is not related to a change in the oxygen percentage but to the increase in partial pressure (corresponding to the increase in total pressure).

The output of the device is not compensated for barometric 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.

Measurements in humidified gas streams should be compensated for by decreasing the oxygen reading 0.03% for each % increase in relative humidity.

**Effect of Electromagnetic Radiation**
Tested over a 80 MHz to 1000 MHz electromagnetic field, the devices are susceptible at all frequencies tested.

Never operate the devices near equipment capable of emitting electromagnetic radiation (EMI) or radio frequency interference (RFI). Do not continue to operate the analyzer if the reading becomes unstable. Consult the Troubleshooting guide in section 8.

**Effect of Electrostatic Discharge (ESD)**
Tested for both Air (insulated surfaces) and Contact (conductive surfaces) Discharge, the devices are susceptible to both.

Never operate the devices without first discharging (ESD) from yourself. Do not continue to operate the analyzer if the reading becomes unstable. Consult the Troubleshooting guide in section 8.

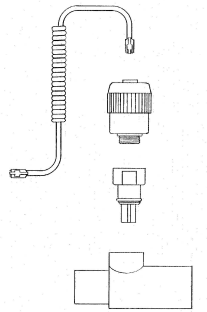
**Calibration**
Calibrating the analyzer or monitor during normal operation involves the same precautions and procedures as those described in Sections 4.7 Start-up Calibration with the same cautions to review Sections 3 Safety Warnings and 5.2 Application Considerations.

**5.3 Sampling**
Assuming the START-UP instructions are followed and the 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.



**5.3.1 Flowing Gas Streams (Breathing Circuits)**
1. Place the sensing area of the sensor into the gas stream to be analyzed upstream of any humidification equipment.
2. The flow rate of the gas stream should not create backpressure by exceeding 10 liters per minute with 1/4" connecting tube AII-2000 HC or 80 liters per minute with 15 mm tee adapter/tube AII-2000 A, M.
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.

**5.3.2 Static Atmospheres (Incubators, Hoods, Oxygen Tents)**
Remove the flow diverter, not needed. Failure to remove the flow diverter will dramatically slow the response time of the sensor.

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 Application Consideration, Effect of Temperature.

### 5.3.3 AII 2000HC Oxygen Analyzer (Integral Oxygen Sensor)

AII 2000HC with its integral oxygen sensor requires connecting the ¼" tubing supplied (section 4.2.1 above) with the device to a ¼" hose barb attached to a pressure regulator controlling a source of gas flowing at less than 10 liters per minute.

### 5.4 Alarms (AII 2000M Oxygen Monitor):

The monitor is equipped with user selectable HI and LO alarm set points which are displayed at the bottom of the LCD. Section 3.6 describes the operation and procedure for setting the alarms in detail.

# 6 Maintenance

Review section 2 General Safety and section 8 Troubleshooting for guidelines on servicing the devices.

### 6.1 Serviceability

Do not open the main compartment of the analyzer, except to replace the oxygen sensor. 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

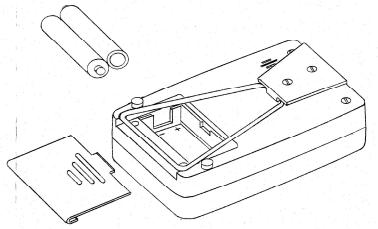
The analyzers and monitor are powered by two AA alkaline batteries with an approximate life of 1,200 hours. A low battery indicator circuit monitors the battery supply voltage and sends a signal directly to the LCD when the battery voltage reaches a preset level that activates the battery symbol in the LCD.

The batteries are housed in a separate compartment located at the rear of the device and are accessible by sliding the removable cover.



Initially this procedure can be somewhat difficult. Care should be taken not to damage the case when removing the battery compartment cover.

### 6.2.1 Procedure:



1. Turn the device over so the shortest raised line on the battery compartment cover is pointing away from you.
2. Lift the tripod wire stand up and away from the case.
3. Grasp the case with both hands and using your thumbs press down firmly on the raised lines and push the battery compartment cover away from you.
4. Locate the positive (+) and negative (-) terminals on the battery.
5. Assure the battery contacts are clean.
6. Align one battery's positive (+) terminal with the corresponding (+) battery symbol molded into the case.
7. Insert the battery into the compartment.
8. Repeat with the remaining battery.
9. Replace the battery compartment cover, make sure it snaps into position and is secured flush against the case. Replace the wire stand as required.
10. Calibrate the device after replacing the batteries.

### 6.3 Oxygen Sensor Replacement

The design of the electronics is intended for only the Analytical Industries Inc. AII-11-60 or AII-11-60-HC Oxygen Sensors. Use of a different oxygen sensor may result in an erroneous oxygen reading.

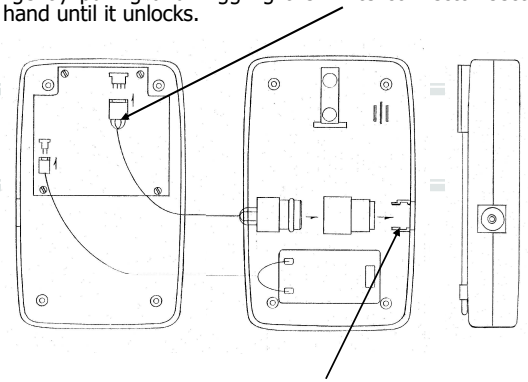
**NEVER -** Open the oxygen sensor or probe the sensing surface, refer to Section 10 in the event the sensor should leak and someone comes in contact with the electrolyte from inside the sensor.

### 6.3.1 Procedure AII 2000M and AII 2000A - External Sensor

1. Disconnect the cable from the old sensor just as you disconnect a telephone jack from a wall plug.
2. To connect the new sensor simply find and register the male plug at the end of the coiled cable and insert it into the mating female jack at the rear of the sensor until it mates or snaps into place.
3. Calibrate the device after replacing the oxygen sensor.

### 6.3.2 Procedure AII 2000HC - Integral Sensor

1. Tools required: small bladed screwdriver.
2. Place the device face down on a flat surface.
3. Remove the two (2) screws from the upper corners of the rear of the device.
4. Move the tripod up, remove the battery compartment cover (see Battery Replacement) and remove the two (2) screws located on either side.
5. Pull the rear section up ¼"-½", turn it over and lay it next to the other section.
6. Locate the white connector at the end of the four (4) wires running from the sensor (the cylinder with the white label) to the top of the PCB.
7. With your left for finger and thumb, grasp the sides of the back end of the white connector where it is soldered to the PCB.
8. With your right fore finger and thumb, grasp the sides of the section of the white connector where the four (4) wires from the sensor terminate.
9. Separate the connector - hold the white connector section your left hand while gently pulling and wiggling the white connector section with your right hand until it unlocks.



10. The oxygen sensor inserts into an adaptor (identified by a round recess with a cylindrical hose adapter in the center) that slides into grooves molded into the side of the case.
11. Hold the rear section of the case down, grasp the square edges of the adaptor, lift up (lift straight up so as not to strip the grooves molded into the adaptor and case) and remove the adaptor and oxygen sensor as a single component.



12. Once the adapter and old sensor have been removed from the case, hold the label of the sensor, again grasp the square edges of the adaptor and pull – to separate the old sensor from the adaptor.
13. Remove the new oxygen sensor from the plastic shipping container.
14. Install the new oxygen sensor by reversing steps 12 through 3.
15. Calibrate the device after replacing the oxygen sensor.

### 6.4 Sensor Life Expected & Warranty

Considers the range of the sensor's signal output, e.g. 3.5-5.5 mV, in meeting the published specification. The overall sensor life is developed as:

- 60 months Expected Service Life 915,420 oxygen % hours
- 6 months Recommended Storage Life period 91,542 % oxygen hours
- 2 months margin of error

At the specified oxygen concentration (air 20.9%), temperature (25ºC/77ºF) and pressure (1 atm), expect 66 months of life whether in storage or in use.

The warranty period of 18 months starts with the shipment date from the factory and is limited to the first claim submitted and is based on:

- 60 months Expected Service Life 915,420 % oxygen hours @ 20.9%
- Estimated exposure (24/7) to 60-70% oxygen concentration
- Marginal of error of 2 months

# 7 Spare Parts & Accessories

| AII-2000 A, AII-2000 M | AII-2000 HC |
|---|---|
| **Spare Parts:** | **Spare Parts:** |
| AII-11-60 Oxygen Sensor | AII-11-60-HC Oxygen Sensor |
| BATT-1008 Battery (2x) 1.5V AA | BATT-1008 Battery (2x) 1.5V AA |
| P-1087 Instructions for Use | P-1087 Instructions for Use |
| A-1162 PCB Assembly Main | A-1162 PCB Assembly Main |
| ENCL-1061 V-mount Retainer | ENCL-1061 V-mount Retainer |
| ENCL-1066 Tripod Wire Stand | ENCL-1066 Tripod Wire Stand |
| CABL-1006 Coil Cable | TUBE-1007 1/4" Tubing 7' |
| FITN-1009 Blue Tee Adapter | |
| FITN-1112-1 Flow Diverter | |
| **Optional Accessories:** | **Optional Accessories:** |
| HRWR-1075 Dovetail Clamp | FITN-1066 Nipple Universal |
| ENCL-1052 Carrying Case | HRWR-1074 Dovetail Clamp |
| | ENCK-1052 Carrying Case |

# 8 Troubleshooting

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

| Symptom | Corrective Action |
|---|---|
| Device fails START-UP TESTS | Repeat, if unsuccessful DO NOT use and contact factory. |
| Device appears to be physically damaged | Turn device ON, if START-UP TESTS and calibration successful – proceed. |
| No digital display when device is turned ON | Install, replace, check polarity of battery.<br>Check and/or clean battery contacts<br>Discharge (ESD) from yourself before use, wait 5 minutes. Restart until device passes START-UP TESTS and recalibrate.<br>If problem persists, DO NOT use the device and contact factory. |
| Battery symbol on LCD display | Replace battery and calibrate device |
| LCD display reads 00.0 | Install sensor<br>Check electrical connections<br>Assure electrical connections are dry |
| No response to keypad action | Replace battery<br>Replace keypad (contact factory) |
| Cannot turn device OFF | Calibration routine in process – escape or wait until completed |
| Reading displayed by LCD drifts during calibration | Place sensor on flat surface (not in your hand), wait 5 min and repeat calibration<br>Check integrity of gas delivery system<br>Check sensor's front o-ring seal<br>Verify calibration gas in not humidified<br>Remove moisture covering sensor<br>Replace sensor, repeat calibration |
| Reading climbs after calibration in 100% dry oxygen when exposed to air 20.9% | Allow the sensor to stabilize for 5 minutes in 100% dry oxygen and recalibrate |
| After calibration in 100% dry oxygen, analyzer reading drifts more than 2% over 8 hours | Check primary oxygen delivery device<br>Replace sensor that is nearing the end of its useful life |



| Symptom | Corrective Action |
|---|---|
| Reading displayed by LCD does not change when oxygen level changes | Replace sensor |
| Reading does not stabilize or fluctuates erratically | Relocate analyzer away source of radio frequency or electromagnetic radiation emissions. Devices are susceptible at all frequencies tested.<br>Check sensor connection<br>Check cable connection<br>Wait 5 minutes and repeat calibration<br>Replace sensor, repeat calibration<br>DO NOT use the device and contact factory. |
| Reading displayed by LCD does not change when calibration control is adjusted | Replace sensor |
| Reading displayed by LCD is very low | Check sensor connection<br>Check cable connection<br>Replace sensor |
| Alarms continuously activated | None – Normal operation, confirm set points<br>Abnormal -<br>▶ Adjust alarm set points<br>▶ Remove moisture covering sensor<br>▶ Check sensor connection<br>▶ Check cable connection<br>▶ Check integrity of gas delivery system<br>▶ Check sensor's front o-ring seal<br>▶ Verify calibration gas in not humidified<br>▶ Verify flow rate is 4-5 liters per minute<br>▶ Replace sensor<br>▶ Replace cable |

# 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 Inc., 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 Inc. shall not be 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 Safety Data Sheet (SDS)

| | |
|---|---|
| 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;<br>eye - corrosive, possible loss of vision;<br>skin contact - corrosive, possible chemical burn.<br>Liquid inhalation is unlikely.<br>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.

## Technical Specifications

| | |
|---|---|
| Application: | The AII-2000 A, HC Oxygen Analyzers are intended for short term use in combination with therapeutic devices such as lung ventilators and incubators; monitoring vital physiological processes and parameters such as respiration, anesthesia, intensive or emergency care; monitoring the administration of gases using ventilators, anesthesia machines, hyperbaric chambers and medical gas mixers.<br><br>The AII-2000 A, HC Oxygen Analyzers measure and displays an independent secondary confirmation of the oxygen concentration in breathing gases administered by other devices. |
| Analysis: | 0-100% oxygen |
| Accuracy: | Less than ± 1% of FS range under constant conditions and ±5% over the operating range |
| Application Considerations: | ♦ Anesthetic agents: Complies with ISO 80601-2-55 for the maximum error allowable over a given duration.<br>♦ Temperature: Signal output and expected life change 2.54% per 1°C. Signal output is compensated within following ambient calibration, step changes of 15°C require 30-60 minutes to equilibrate.<br>♦ Pressure: Signal output and expected life change proportionally. Accurate at any pressure provided it is constant, change is gradual simulating the human lung and the device is calibrated at the pressure of the sample gas.<br>♦ Humidity: Non-condensing RH has no effect. Adding water vapor to the sample reduces the oxygen concentration.<br>♦ Condensation: Causes erroneously readings if allowed to cover the sensing area or collect on electrical connections.<br>♦ Electromagnetic Radiation: Susceptible to interference over frequencies from 26 MHz to 1000 MHz. |
| Calibration: | Air or certified 100% $O_2$ before use or every 8 hours, after disconnecting or replacing the batteries or oxygen sensor |
| Cleaning: | Wipe components with a soft cloth dampened with water or mild 70% isopropyl alcohol solution in water. |
| Compensation: | Temperature |
| Connections: | 1x16 mm thread or push-in flow diverter with o-ring seal |
| Controls: | Soft touch keypad for ON/OFF and menu function |
| Dimensions: | 3.6 x 5.9 x 1.6"; weight 10 oz. (280 grams) |
| Display: | 3-1/2 digit backlit LCD 2.75 x 1.375; resolution 0.1% $O_2$ |
| Flow Sensitivity: | None; < 10 lpm with 1/4" tube AII-2000 HC;<br>< 80 lpm with 15mm tee adapter/tube AII-2000 A, M |
| Humidity: | Non-condensing 0-95% RH |
| Linearity: | ± 1% under constant conditions |
| Mounting: | Flat surface for tripod extension or dovetail V-mount |
| Operating Range: | 5º to 45ºC (41ºF to 113ºF) |
| Power: | 2 AA Alkaline batteries; 1,200 hours of 24/7 use |
| Pressure: | Inlet - ambient or regulated; vent - atmospheric |
| Power: | 2 AA Alkaline batteries; 1,200 hours of 24/7 use |
| Response: | 90% of final FS reading in 10 seconds |
| Sampling: | 'A version' Ambient-remove flow diverter; flowing gas-install flow diverter, insert into tee-adaptor and position face down; 'HC version" Connect 1/4" tubing to gas fitting on right side. |
| Sensitivity: | < 0.5% of FS range |
| Sensor: | 'A version' AII-11-60; 'HC version' AII-11-60-HC |
| Sensor Life: | 60 months in air at 25ºC and 1 atm |
| Storage: | 0º to 45ºC (32ºF to 113ºF) on intermittent basis |
| Warm-up: | None |
| Warranty: | 24 months analyzer; 18 months sensor |

## Optional Equipment

HRWR-1075 Dovetail Pole/Shelf Clamp, CC-1072 Carrying Case


**AII-2000 A**
**Oxygen Analyzer**


**AII-2000 HC**
**Oxygen Analyzer**

**Manufactured under an independently certified Quality Management System**

CE 0123

2855 Metropolitan Place, Pomona, CA 91767 USA ♦ Tel: 909-392-6900, Fax: 909-392-3665, www.aii1.com, e-mail: info@aii1.com Rev 5/18

## Technical Specifications

| | |
|---|---|
| Application: | The AII-2000 M Oxygen Monitor is intended for short term use in combination with therapeutic devices such as lung ventilators and incubators; monitoring vital physiological processes and parameters such as respiration, anesthesia, intensive or emergency care; monitoring the administration of gases using ventilators, anesthesia machines, hyperbaric chambers and medical gas mixers.<br><br>The AII-2000 M Oxygen Monitor measures and displays an independent secondary confirmation of the oxygen concentration in breathing gases administered by other devices. |
| Analysis: | 0-100% oxygen |
| Accuracy: | Less than ± 1% of FS range under constant conditions and ±5% over the operating range |
| Application Considerations: | ♦ Anesthetic agents: Complies with ISO 80601-2-55 for the maximum error allowable over a given duration.<br>♦ Temperature: Signal output and expected life change 2.54% per 1°C. Signal output is compensated within ±5% over the operating temperature range following ambient calibration, step changes of 15°C require 30-60 minutes to equilibrate.<br>♦ Pressure: Signal output and expected life change proportionally. Accurate at any pressure provided it is constant, change is gradual simulating the human lung and the device is calibrated at the pressure of the sample gas.<br>♦ Humidity: Non-condensing RH has no effect. Adding water vapor to the sample reduces the oxygen concentration.<br>♦ Condensation: Causes erroneously readings if allowed to cover the sensing area or collect on electrical connections.<br>♦ Electromagnetic Radiation: Susceptible to interference over frequencies from 26 MHz to 1000 MHz. |
| Alarms: | Adjustable HI 16-100% and LO 15-99% alarms with LED indicators; 120 second alarm silence for calibration purposes; HI alarm defeat for flushing patients with 100% $O_2$ |
| Calibration: | Air or certified 100% $O_2$ every 8 hours; and, after disconnecting or replacing the batteries or oxygen sensor |
| Cleaning: | Wipe components with a soft cloth dampened with water or mild 70% isopropyl alcohol solution in water. |
| Compensation: | Temperature |
| Connections: | 1x16 mm thread or push-in flow diverter with o-ring seal |
| Controls: | Soft touch keypad for ON/OFF and menu function |
| Dimensions: | 3.6 x 5.9 x 1.6″; weight 10 oz. (280 grams) |
| Display: | 3-1/2 digit backlit LCD 2.75 x 1.375; resolution 0.1% $O_2$ |
| Flow Sensitivity: | None; < 10 lpm with 1/4″ tube AII-2000 HC ;<br>< 80 lpm with 15 mm tee adapter/tube AII-2000 A, M |
| Humidity: | Non-condensing 0-95% RH |
| LED Indicators: | Activation of alarm condition |
| Linearity: | ± 1% under constant conditions |
| Mounting: | Flat surface for tripod extension or dovetail V-mount |
| Operating Range: | 5º to 45ºC (41ºF to 113ºF) |
| Power: | 2 AA Alkaline batteries; 1,200 hours of 24/7 use |


**AII-2000 M**
**Oxygen Monitor**

## Technical Specifications cont'd

| | |
|---|---|
| Pressure: | Inlet - ambient or regulated; vent - atmospheric |
| Response: | 90% of final FS reading in 10 seconds |
| Sampling: | Ambient-remove flow diverter; flowing gas-install flow diverter, insert into tee-adaptor and position with sensing area facing downward |
| Sensitivity: | < 0.5% of FS range |
| Sensor: | AII-11-60 Oxygen Sensor |
| Sensor Life: | 60 months in air at 25ºC and 1 atm |
| Storage: | 0º to 45ºC (32ºF to 113ºF) on intermittent basis |
| Warm-up: | None |
| Warranty: | 24 months analyzer; 18 months sensor |

## Optional Equipment

HRWR-1075 Dovetail Pole/Shelf Clamp

CC-1072 Carrying Case

**Manufactured under an independently certified Quality Management System**

CE 0123

2855 Metropolitan Place, Pomona, CA 91767 USA ♦ Tel: 909-392-6900, Fax: 909-392-3665, www.aii1.com, e-mail: info@aii1.com Rev 5/18

# 12 Declaration of Conformity

| | | | |
|---|---|---|---|
| Certificate No.: | Q5 096122 0008 Rev. 00 | QS6 096122 0010 Rev. 00 | QS5 096122 009 Rev. 00 |
| Certificate Holder / Manufacturer: | Analytical Industries Inc., 2855 Metropolitan Place, Pomona, California 91767 USA<br>Tel: 909-392-6900, Fax: 909-392-1665, e-mail: sales-medical@aii1.com | | |
| EU Authorized Representative: | Distribuciones y Resoresentaciones Biomedicas Direx, S.L<br>Avda. San Pablo, 28. Nave 24, 2882 Coslada Madrid, Espana<br>Tel: 34 902-12 14 75, Fax: 34 902-56 24 38, email: compras@direx.net | NA | |
| Scope: | Quality Assurance System for Design and Development Production and Distribution of Oxygen Sensors, Oxygen Analyzers and Oxygen Monitors for Medical Applications | Design, Manufacture and Distribution of Oxygen Sensors, Analyzers and Monitors for Medical Applications | Design, Manufacture, Service and Distribution of Oxygen Sensors, Analyzers and Monitors for Industrial Applications |
| Directive/Standard: | 93/42/EEC on Medical Devices (MDD),<br>Annex II excluding section 4 | ISO 13485:2016, MDSAP | ISO 9001:2015 |
| Classification: | IIb per Annex IX, Section 2.2, Sub-section 3, Rule 9 | IIb | NA |
| Product Categories: | Oxygen Sensors, Analyzers and Monitors (Attachment A) | | Analyzers, Transmitters, Monitors Oxygen Sensors www.aii1.com |
| Report No.: | 72141732 | NA | 72141732 |
| Expiry Date: | 2022-02-28 | 2022-02-003 | |
| Notified Body: | TÜV SUD Product Service GmbH, Zertifizierstelle,<br>Riddlerstrasse 65, D-20339, München, Germany No.: 0123 | TUV SUD America Inc., 10 Centennial Drive,<br>Peabody, MA 01960 USA | |
| Applied Standards: | EN ISO 13485:2012/AC:2012 Medical devices - Quality management systems - Requirements for regulatory purposes<br>ISO 80601-22-55 Medical electrical equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors | See ATEX / IECEx Declaration of Conformity | |
| | Directive 2011/65/EU (recast) June 8, 2011 on the restriction of hazardous substances in electrical and electronic equipment (RoHS), specifically Article 4 (1-6) and 13; Annex IV and VI | | |
| Date CE mark affixed: | February 21, 2006 | | |

Effective 4 February 2019, on behalf of Analytical Industries Inc., I declare and assume the responsibility that the above products, traceable by date coded serial numbers are in compliance with and meet the provisions of the directives and standards above. All supporting documents are retained on the premises of the manufacturer and the notified body.

Patrick Prindible, Vice President

Rev 12 12/20/2019

Page 1 of 4

# 12 Declaration of Conformity

## Attachment A

| Product Group | Model No. (1) | Model Name | Classification (2) | UMDNS No. | UDI / GUDID No. | HC License No. |
|---|---|---|---|---|---|---|
| Oxygen Analyzer | AU-2000-A | Oxygen Analyzer | IIb | 12863 | 00897772002000 | 66229 |
| Oxygen Analyzer | AU-2000-Palm-O2 | Oxygen Analyzer | IIb | 12863 | 00897772002468 | 66229 |
| Oxygen Analyzer | AU-2000-Palm-O2-R | Oxygen Analyzer | IIb | 12863 | 00897772002505 | 66229 |
| Analyzer Accessory | FITN-1009 | Disposable Tee Adapter | IIb | 12863 | M996BE1251TD0 | 66229 |
| Analyzer Accessory | FITN-1009-PH | Disposable Tee Adapter | IIb | 12863 | M996BE1251TD0 | 66229 |
| Oxygen Analyzer | AU-2000-HC | Oxygen Analyzer | IIb | 12863 | 00897772002024 | 66993 |
| Analyzer Accessory | A-3675-1 | Home Care Kit | IIb | 12863 | M996BE1251TD0 | 66993 |
| Analyzer Accessory | TUBE-1007 | Tubing Plastic | IIb | 12863 | M996BE1251TD0 | 66993 |
| Oxygen Monitor | AU-2000M | Oxygen Monitor | IIb | 12858 | 00897772002017 | 70298 |
| Monitor Accessory | FITN-1009 | Disposable Tee Adapter | IIb | 12858 | M996BE1251TD0 | 70298 |
| Monitor Accessory | FITN-1009-PH | Disposable Tee Adapter | IIb | 12858 | M996BE1251TD0 | 70298 |
| Oxygen Sensor | PSR-11-75-KE250-A | Oxygen Sensor | IIb | 13538 | 00897772002529 | 92498 |
| Oxygen Sensor | AU-11-75-PO2 | Oxygen Sensor | IIb | 13538 | 00897772002451 | 92498 |
| Oxygen Sensor | PSR-11-917-MH2 | Oxygen Sensor | IIb | 13538 | 00897772002444 | 92498 |
| Oxygen Sensor | PSR-11-915-2 | Oxygen Sensor | IIb | 13538 | 00897772002277 | 92498 |
| Oxygen Sensor | PSR-11-77 | Oxygen Sensor | IIb | 13538 | 00897772002246 | 92498 |
| Oxygen Sensor | PSR-11-75-KE2 | Oxygen Sensor | IIb | 13538 | 00897772002161 | 92498 |
| Oxygen Sensor | PSR-11-917-J1 | Oxygen Sensor | IIb | 13538 | 00897772002116 | 92498 |
| Oxygen Sensor | PSR-11-58-HC | Oxygen Sensor | IIb | 13538 | 00897772002093 | 92498 |
| Oxygen Sensor | PSR-11-75-KE84 | Oxygen Sensor | IIb | 13538 | 00897772002673 | 92498 |
| Oxygen Sensor | PSR-11-917-MHT | Oxygen Sensor | IIb | 13538 | 00897772002635 | 92498 |
| Oxygen Sensor | PSR-11-917-MHJ | Oxygen Sensor | IIb | 13538 | 00897772002598 | 92498 |
| Oxygen Sensor | PSR-11-917-MH1J 1111227" | Oxygen Sensor | IIb | 13538 | 00897772002581 | 92498 |
| Oxygen Sensor | PSR-11-917-J6 | Oxygen Sensor | IIb | 13538 | 00897772002567 | 92498 |
| Oxygen Sensor | PSR-11-77-CT4 | Oxygen Sensor | IIb | 13538 | 00897772002543 | 92498 |
| Oxygen Sensor | PSR-11-55-HL | Oxygen Sensor | IIb | 13538 | 00897772002512 | 92498 |
| Oxygen Sensor | PSR-11-917-MCC CAT-644-PE" | Oxygen Sensor | IIb | 13538 | 00897772002475 | 92498 |
| Oxygen Sensor | PSR-11-60-08 | Oxygen Sensor | IIb | 13538 | 00897772002321 | 92498 |
| Oxygen Sensor | PSR-11-915 | Oxygen Sensor | IIb | 13538 | 00897772002260 | 92498 |

# 12 Declaration of Conformity

## Attachment A

| Product Group | Model No. (1) | Model Name | Classification (2) | UMDNS No. | UDI / GUDID No. | HC License No. |
|---|---|---|---|---|---|---|
| Oxygen Sensor | PSR-11-917-M<br>ERT-BMCF-1968-01*<br>68289* | Oxygen Sensor | IIb | 13538 | 00897772002215 | 92498 |
| Oxygen Sensor | PSR-11-75-KE8<br>ERT-S5-1968-04* | Oxygen Sensor | IIb | 13538 | 00897772002208 | 92498 |
| Oxygen Sensor | PSR-11-75-KE7 | Oxygen Sensor | IIb | 13538 | 00897772002192 | 92498 |
| Oxygen Sensor | PSR-11-917-J2 | Oxygen Sensor | IIb | 13538 | 00897772002123 | 92498 |
| Oxygen Sensor | PSR-11-33-2 | Oxygen Sensor | IIb | 13538 | 00897772002062 | 92498 |
| Oxygen Sensor | PSR-11-33-1 | Oxygen Sensor | IIb | 13538 | 00897772002055 | 92498 |
| Oxygen Sensor | PSR-11-33<br>51250* | Oxygen Sensor | IIb | 13538 | 00897772002048 | 92498 |
| Oxygen Sensor | PSR-11-917-2S | Oxygen Sensor | IIb | 13538 | 00897772002734 | 92498 |
| Oxygen Sensor | PSR-11-917-14F | Oxygen Sensor | IIb | 13538 | 00897772002710 | 92498 |
| Oxygen Sensor | PSR-11-37-202-2<br>3902646-00* | Oxygen Sensor | IIb | 13538 | 00897772002697 | 92498 |
| Oxygen Sensor | PSR-11-917-M204 | Oxygen Sensor | IIb | 13538 | 00897772002680 | 92498 |
| Oxygen Sensor | PSR-11-75-KE13-PB | Oxygen Sensor | IIb | 13538 | 00897772002611 | 92498 |
| Oxygen Sensor | PSR-11-917-J5 | Oxygen Sensor | IIb | 13538 | 00897772002550 | 92498 |
| Oxygen Sensor | PSR-11-75-KEFR | Oxygen Sensor | IIb | 13538 | 00897772002536 | 92498 |
| Oxygen Sensor | PSR-11-917-MH3 | Oxygen Sensor | IIb | 13538 | 00897772002499 | 92498 |
| Oxygen Sensor | PSR-11-60-3<br>ERT-P-1968-05* | Oxygen Sensor | IIb | 13538 | 00897772002482 | 92498 |
| Oxygen Sensor | PSR-11-75-KE10+ | Oxygen Sensor | IIb | 13538 | 00897772002420 | 92498 |
| Oxygen Sensor | AU-11-60-HC | Oxygen Sensor | IIb | 13538 | 00897772002390 | 92498 |
| Oxygen Sensor | PSR-11-60-23A | Oxygen Sensor | IIb | 13538 | 00897772002338 | 92498 |
| Oxygen Sensor | PSR-11-915-1 | Oxygen Sensor | IIb | 13538 | 00897772002291 | 92498 |
| Oxygen Sensor | PSR-11-915-21 | Oxygen Sensor | IIb | 13538 | 00897772002284 | 92498 |
| Oxygen Sensor | PSR-11-917-MH<br>51254*<br>396008* | Oxygen Sensor | IIb | 13538 | 00897772002239 | 92498 |
| Oxygen Sensor | PSR-11-917-M1 | Oxygen Sensor | IIb | 13538 | 00897772002222 | 92498 |
| Oxygen Sensor | PSR-11-75-KE6<br>ERT-S2-1968-03* | Oxygen Sensor | IIb | 13538 | 00897772002185 | 92498 |
| Oxygen Sensor | PSR-11-917-J3 | Oxygen Sensor | IIb | 13538 | 00897772002130 | 92498 |
| Oxygen Sensor | PSR-11-75-KE1-HO2 | Oxygen Sensor | IIb | 13538 | 00897772002666 | 92498 |
| Oxygen Sensor | PSR-11-917-JF | Oxygen Sensor | IIb | 13538 | 00897772002659 | 92498 |

# 12 Declaration of Conformity

## Attachment A

| Product Group | Model No. (1) | Model Name | Classification (2) | UMDNS No. | UDI / GUDID No. | HC License No. |
|---|---|---|---|---|---|---|
| Oxygen Sensor | PSR-11-917-JPH 1099812* | Oxygen Sensor | IIb | 13538 | 00897772002642 | 92498 |
| Oxygen Sensor | PSR-11-75-KE1-250X | Oxygen Sensor | IIb | 13538 | 00897772002628 | 92498 |
| Oxygen Sensor | PSR-11-917-J7 | Oxygen Sensor | IIb | 13538 | 00897772002574 | 92498 |
| Oxygen Sensor | PSR-11-917-M2 | Oxygen Sensor | IIb | 13538 | 00897772002406 | 92498 |
| Oxygen Sensor | PSR-11-58-15 | Oxygen Sensor | IIb | 13538 | 00897772002383 | 92498 |
| Oxygen Sensor | PSR-11-915-4 | Oxygen Sensor | IIb | 13538 | 00897772002314 | 92498 |
| Oxygen Sensor | PSR-11-915-G | Oxygen Sensor | IIb | 13538 | 00897772002253 | 92498 |
| Oxygen Sensor | PSR-11-75-KE1 | Oxygen Sensor | IIb | 13538 | 00897772002154 | 92498 |
| Oxygen Sensor | PSR-11-58 | Oxygen Sensor | IIb | 13538 | 00897772002086 | 92498 |
| Oxygen Sensor | PSR-11-55 | Oxygen Sensor | IIb | 13538 | 00897772002079 | 92498 |
| Oxygen Sensor | PSR-11-917-J8 | Oxygen Sensor | IIb | 13538 | 00897772002703 | 92498 |
| Oxygen Sensor | AU-11-75-PO2-R | Oxygen Sensor | IIb | 13538 | 00897772002468 | 92498 |
| Oxygen Sensor | PSR-11-75-KE9 66045* | Oxygen Sensor | IIb | 13538 | 00897772002413 | 92498 |
| Oxygen Sensor | PSR-11-917-MH1 TND-S0201* | Oxygen Sensor | IIb | 13538 | 00897772002369 | 92498 |
| Oxygen Sensor | PSR-11-75-KE | Oxygen Sensor | IIb | 13538 | 00897772002345 | 92498 |
| Oxygen Sensor | PSR-11-915-3 | Oxygen Sensor | IIb | 13538 | 00897772002307 | 92498 |
| Oxygen Sensor | PSR-11-75-KE4 ERT-V-1968-02* Z775-001* | Oxygen Sensor | IIb | 13538 | 00897772002178 | 92498 |
| Oxygen Sensor | PSR-11-917-J 1001454* | Oxygen Sensor | IIb | 13538 | 00897772002109 | 92498 |
| Oxygen Sensor | AU-11-60 | Oxygen Sensor | IIb | 13538 | 00897772002031 | 92498 |

(1) * Private Label / Same Part

(2) MDD 93/42/EEC Annex IX, Sec 2.2, Sub Sec 3, Rules 9,10,11

Rev 12 12/20/2019

Page 4 of 4

# 13 Quality Control & Calibration Certification

| | | | | |
|---|---|---|---|---|
| Customer: | _____ | | Date: _____ | |
| Order No. | _____ | | | Pass Y/N Initial / Date |
| Model: | ( ) AII-2000 A Oxygen Analyzer<br>( ) AII-2000 HC Oxygen Analyzer<br>( ) AII-2000 M Oxygen Monitor ( ) AII-2000 M-PH Oxygen Monitor S/N | | _____ | _____ |
| Sensor: | ( ) AII-11-60 Oxygen Sensor<br>( ) AII-11-60-HC Oxygen Sensor | S/N | _____ | _____ |
| Electronics: | A-1152 Rev H PCB Assembly Main | S/N: _____ | Software Ver. _____ | _____ |
| Accessories: | P-1087 Manual, Instructions for Use<br>BATT-1008 Battery, 1.5V AA (Qty 2) | | | _____ |
| | AII-2000 A/M:<br>CABL-1006 Cable, Coiled Phone Jack<br>FITN-1112-1 Flow Diverter<br>( ) FITN-1009 Blue Tee Adapter ( ) FITN-1009-PH Blue Tee Adapter | | | _____ |
| | AII-2000 HC:<br>A-3675-1 1/4" Tubing 7 ft. with Adapter | | | _____ |
| **Tests:** | **Pass**: Observed Value within Expected Value | **Fail**: Observed Value outside of Expected Value | | |
| | | **Expected Value** | **Observed Value** | **Initial / Date** |
| | Unit passes internal start-up tests | PASS | P / F | |
| | Reading in air after air calibration (Calibration) | 20.9% ±0.2% O2 | | |
| | Reading after exposure to 100% O2 (Linearity) | 100% ±2.0% O2 | | |
| | Reading in air after exposure to 100% O2 (Accuracy) | 20.9% ±2.0% O2 | | |
| | Reading in 100% O2 after 100% O2 calibration (Calibration) | 100% ±0.2% O2 | | |
| | Reading fluctuation on 100% O2 for 5 minutes (Noise) | < 1.0% O2 | | |
| | Reading over 5 minutes on 100% O2 (Drift) | 100% ±2.0% O2 | | |
| | Reading in air after 100% O2 calibration (Linearity) | 20.9% ±2.0% O2 | | |
| | Reading in 100% O2 after exposure to air (Accuracy) | 100% ±2.0% O2 | | |
| | Overall inspection for physical defects | | | _____ |
| Options: | P/N _____ | | Qty _____ | _____ |
| | Spare Parts: P/N _____ | | Qty _____ | _____ |
| Delivery: | 1 of ____ , ship by _____ | | | _____ |