NORTH AMERICAN DRAGER

Instruction Manual

OXYMED

OXYGEN ANALYZER

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GENERAL DESCRIPTION

The Oxymed is an oxygen concentration monitor (oxygen analyzer) intended to be used primarily in a Narkomed 2A anesthesia system. It utilizes a dual galvanic cell sensor to measure oxygen concentration in the patient circuit. The oxygen concentration is displayed in percent oxygen and is continuously compared to preset alarm limits. Should an alarm condition occur, both visible and audible indicators are produced. In addition to these basic functions, the Oxymed contains an automatic calibration procedure, a digital communications interface, and many self-diagnostic and patient protection features.

FEATURES

DISPLAYS: The measured oxygen concentration as well as the low oxygen alarm limit is continuously displayed in digital format.

ALARMS: The Oxymed incorporates alarms for low and high oxygen concentration. The alarm limits are independently adjustable.

MAIN SWITCH INTERFACE: The Oxymed power is switched by the Narkomed 2A main switch. This ensures that the Oxymed is always active when the Narkomed 2A anesthesia system is used.

AUTO-CALIBRATION: During the pre-operative anesthesia equipment set up, the Oxymed electronics can be calibrated to either 21% or 100% oxygen. During this procedure the Oxymed automatically establishes zeroing and scaling constants used in processing the oxygen concentration information received from the sensor. When the Oxymed is turned off these constants are "remembered" for 12 hours following the time the unit was last calibrated. This feature will prevent the operator from having to calibrate the unit at the beginning of each case, but will assure that the unit is calibrated at least once at the beginning of each normal operating day. Also, during the calibration procedure, sensor life is checked and calibration is inhibited if the sensor is exhausted.

SENSOR ERROR DETECTION: The Oxymed sensor has two cells each of which produce a signal which varies proportionally with the oxygen concentration in the patient circuit. Because of this redundancy the Oxymed can continuously compare these signals. If the difference between the two signals exceeds a predetermined percentage, the operator is alerted.

NAD DATA NETWORK: The Oxymed is capable of communication with other North American Drager monitors. This system allows the measured and calculated values, alarm limits, and alarm conditions of one monitor to be used by other monitors in the system to analyze, display, and record information.

SELF-DIAGNOSTIC CIRCUIT: In the event the Oxymed system fails, an independent timing circuit automatically resets the system. If this circuit fails to work, the self-diagnostic indicator flashes red and green intermittently.

RFI SHIELDING: The main circuit board of the Oxymed is enclosed by a stainless steel shield to minimize radio frequency interference from surrounding equipment.

INSTALLATION

OXYMED MONITOR INSTALLATION

Installation of the Oxymed oxygen analyzer shall be by or under the direction of an authorized representative of North American Drager

OXYMED SENSOR INSTALLATION (see Fig. 1)

1. Insert sensor capsule into connection housing, making sure electrical contacts in the connection housing mate with the copper rings on the capsule.

2. Screw on housing cover as shown.

3. Remove plastic valve dome from inspiratory valve by unscrewing retaining ring and replace original valve dome with valve dome adapter.

4. Insert sensor housing into valve dome adapter as shown.

5. Insert sensor plug into sensor input receptacle on rear panel of Oxymed.

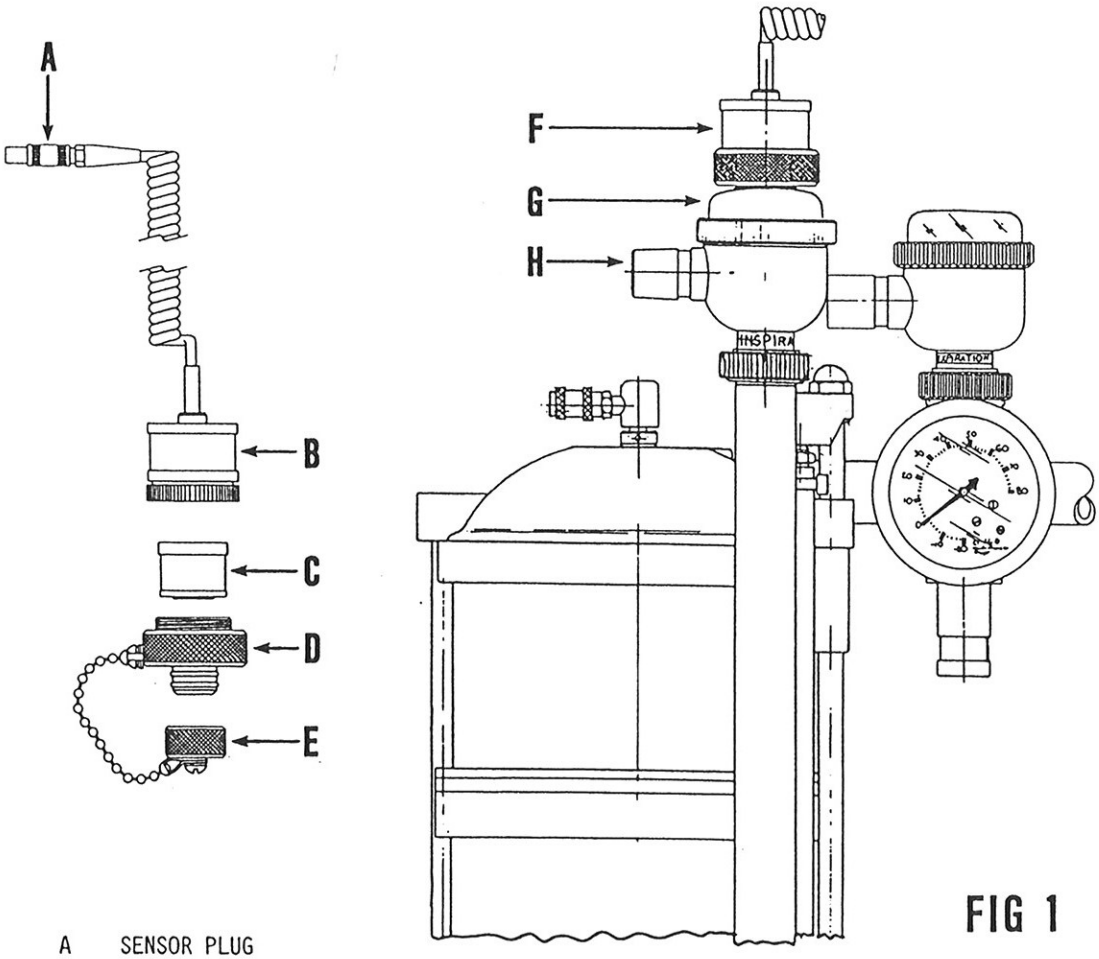

FIG 1

A SENSOR PLUG
B CONNECTION HOUSING
C SENSOR CAPSULE
D HOUSING COVER
E DUST CAP

F OXYMED SENSOR
G VALVE DOME ADAPTER
H INSPIRATORY VALVE

OPERATING INSTRUCTIONS

ACTIVATING THE MONITOR AND OPERATION CHECK

1. POWER-ON INITIALIZATION

ACTION	RESULT
a. Turn on main switch of Narkomed 2A.	a. Unit should show "888" on both percent oxygen and low oxygen limit displays. b. Self-diagnostic indicator should be green - all other indicators should be yellow. c. Audible beep should sound.

Following the power-on initialization the unit will display a percent oxygen (indicating the unit has been calibrated at least once in the last 12 hours) or it will light dashes in both displays and both calibration indicators will remain yellow (indicating calibration was not recently performed). If calibration has been completed, the following step may be omitted. If the Oxymed remains turned on and uncalibrated for longer than 3 minutes, both calibration indicators will remain yellow and a short audible tone will sound.

2. SYSTEM CALIBRATION, IF NECESSARY

ACTION	RESULT
a. Expose sensor to 21% oxygen (room air) or 100% oxygen, whichever is desired. Press the appropriate calibration control button and hold for approximately 1 second. NOTE: the sensor must be exposed to the applicable concentration prior to pressing the calibration control button. A warmup time of 15 minutes is required before calibration if a new sensor capsule has been installed into the sensor housing.	a. The appropriate calibration indicator will remain yellow indicating the automatic calibration procedure has been initiated for that percentage of oxygen (the other calibration indicator is extinguished). After approximately 45 seconds the selected calibration indicator will be lit green indicating the calibration procedure has been completed. Should the unit be unable to be calibrated due to sensor failure or disconnect, both calibration indicators and the sensor status indicator will be lit yellow accompanied by a short audible tone.

As a standard calibration procedure North American Drager recommends a calibration with 21% oxygen (room air). The calibration with 100% oxygen in routine use is more difficult. If such a calibration is necessary, the exposure of the sensor to guaranteed 100% oxygen during the whole calibration process, from pressing the calibration button until the green indicator light appears, is absolutely necessary otherwise the instrument may overstate the measured oxygen concentration.

3. ALARM LIMIT SETTINGS

ACTION	RESULT
a. To set the low alarm limit, press appropriate limit control button to raise or lower limit and hold.	a. As button is pushed the displayed limit will be incremented or decremented slowly at first then more quickly. (If further fine adjustment is necessary, simply release the button and press it again.) The power-on default low limit setting is 30% O_2.
b. To set the high alarm limit, press both increment and decrement control buttons at the same time. Then set the high alarm limit in the same manner as above.	b. The current high limit setting will be displayed in the low oxygen limit display unit 5 seconds after adjustments to that limit have been completed. Then the low limit setting will again be displayed any time you wish to check the current high limit setting, press both increment and decrement buttons.

The high limit cannot be set below the lower limit setting and the low limit cannot exceed the high limit setting.

ALARM CONDITIONS

1. LOW LIMIT WARNING

The Oxymed continuously compares the current oxygen percentage with the preset low limit setting. Should the oxygen concentration fall below the low limit setting, the low limit display will alternately flash "LO" with the low limit setting, the low limit indicator will flash red and an audible alarm will be produced.

2. HIGH LIMIT CAUTION

The Oxymed continuously compares the current oxygen percentage with the preset high limit settings. Should the oxygen concentration exceed the high limit setting the low limit display will alternately flash "HI" with the high limit setting and an intermittent* audible alarm will be produced.

3. SENSOR ERROR ADVISORY

The sensor indicator is lit green when both sensor output signals are consistent. If one of the sensor cells should fail or become degraded beyond useful life, the signals from the two sensor cells will be inconsistent and the sensor indicator will turn yellow thereby alerting the operator to this condition. A brief audible tone is produced to indicate this change of status.

4. CALIBRATION FAILURE ADVISORY

If the Oxymed remains uncalibrated for more than 3 minutes following power-on, then a short audible tone will be produced.

*Intermittent alarms consist of periodic audible tones.

5. UNCALIBRATED SENSOR ADVISORY

If the calculated oxygen percentage exceeds 103% O_2 then both calibration indicators are lit yellow. If the calculated oxygen percentage exceeds 105% O_2 then both calibration indicators remain yellow, an audible tone is produced, and recalibration is required.

6. SYSTEM FAILURE

If an Oxymed system failure should occur then the self-diagnostic indicator will flash red and green intermittently.

OXYMED UNIT PRECAUTIONS

Should the unit fail to "remember" its calibration zeroing and scaling constants when the unit is turned off and calibration was performed within the last 12 hours, the rechargeable batteries within the unit may need to be replaced. In this event an authorized N.A.D. representative shall be notified to service the unit.

OXYMED SENSOR PRECAUTIONS

CAUTION:

1. Under no circumstances shall a Sensor Capsule be removed from its housing except for the replacement of an exhausted Sensor Capsule.

2. If a Sensor Capsule is removed from its housing, a warmup period equal to the period of its removal (up to one week) may be necessary before normal operation of the Oxymed can resume.

TO PROLONG SENSOR LIFE:

1. When not in use, remove the sensor from the patient circuit (valve dome adapter) and cover its port with the dust cap.

2. Do not remove the new sensor capsule from its package until it is to be used.

CLEANING AND STERILIZATION

OXYMED MONITOR - EXTERIOR SURFACE

The Oxymed monitor exterior case may routinely be cleaned with a mild germicidal detergent and warm water. Abrasive materials of any kind should be avoided so as not to scratch the surface. Caution should be exercised not to let any solution enter the monitor's interior. Occasionally the front panel should be wiped down to preserve the visibility of the display panel by using a 5% detergent product.

OXYGEN SENSOR AND SENSOR HOUSING

The oxygen sensor and sensor housing may be gas sterilized in ethylene oxide at a temperature not exceeding 50°C. Following the sterilization with ethylene oxide, the sensor is to be aerated for at least three hours at a temperature not exceeding 45°C.

TROUBLESHOOTING GUIDE

SYMPTOM	POSSIBLE CAUSE	REMEDY
No sound or LED when main switch is turned on.	Power cable not securely connected between Oxymed & Narkomed 2A.	Tighten power cable connections.
Will not "remember" calibration when turned off and on again within 12 hours.	Internal rechargeable batteries not fully charged. OR Rechargeable batteries worn out.	Charge batteries by leaving Oxymed activated. OR Have service man replace batteries.
Oxymed will not calibrate 45 seconds after pressing "21" or "100" button; both calibration LED's are lit yellow.	No sensor capsule in sensor housing. OR Exhausted sensor capsule. OR Sensor cord is not plugged into Oxymed housing. OR Sensor is exposed to incorrect oxygen concentration. OR Sensor capsule had been removed from housing for a prolonged period of time.	Install sensor capsule in sensor housing. Allow 15 min. warmup for new capsule. OR Replace with new sensor capsule. OR Plug in sensor cord. OR Expose sensor to room air for 21% calibration. OR Allow warmup period equal to duration of capsule removal.
Both calibration indicators are lit yellow; both oxygen percentage and low limit displays show dashes.	Oxymed requires calibration.	Expose sensor to room air and press "21" calibrate button.
Sensor indicator lit yellow.	Bad electrical contact between capsule and housing. OR Sensor capsule exhausted. OR Defective sensor housing & cable.	Clean contacts. OR Replace capsule. OR Replace housing.
Oxymed not communicating over Data Network.	Communications loop not complete. OR Not all monitors activated. OR Communications error.	Connect all data cables. OR Turn on all monitors. OR Turn off one monitor, then turn on again.

SERVICE

Preventive Maintenance Contracts are available for all products manufactured by North American Drager. The "Drager Service" agreements are available from the North American Drager Service Department or our Nationwide Factory Trained Service Network.

WARRANTY

The warranty terms set forth in North American Drager's Terms and Conditions (P82-004-IV5M, attached) apply; sensor warranty is limited to three months.

WARNINGS

Federal Law restricts the Oxymed oxygen analyzer to sale by or on the order of a Physician.

SPARE & REPLACEMENT PARTS COMPONENT LIST

6803290	Sensor Capsule
4106363	Sensor Housing
4106410	Power Cable, Oxymed
4106308	Data Network Cable, long
4106309	Data Network Cable, short

SPECIFICATIONS

MONITOR

PHYSICAL

Size: Width 152.4mm (6.0 in.)
Height 50.8mm (2.0 in.)
Length 254.0mm (10.0 in.)

Weight: 2.2 kg (4 lb. 14 oz.)

Front Panel Displays and Indicators (see Fig. 2)

Percent Oxygen Display:	3 digit, 7.6mm (.300 in.), 7-segment, red L.E.D.	(A)
Low Oxygen Limit:	3 digit, 3.7mm (.150 in.), 7-segment, red L.E.D.	(B)
100% Calibration Indicator:	3.18mm (.125 in.), green/yellow L.E.D.	(C)
21% Calibration Indicator:	3.18mm (.125 in.), green/yellow L.E.D.	(D)
Low Oxygen Indicator:	3.18mm (.125 in.), red L.E.D.	(E)
Sensor Indicator:	3.18mm (.125 in.), green/yellow L.E.D.	(F)
Self-Diagnostic Indicator:	3.18mm (.125 in.), red/green L.E.D.	(G)

Front Panel Controls (see Fig. 2)

Limit Decrement Control:	momentary pushbutton	(H)
Limit Increment Control:	momentary pushbutton	(I)
100% Calibration Control:	momentary pushbutton	(K)
21% Calibration Control:	momentary pushbutton	(L)

Rear Panel Connections (see Fig. 3)

Sensor Input Connection:	circular, keyed, female, 3-contact, Lemo #RGF0B303CA228	(M)
NAD Data Network Output Connection:	male DB15 receptacle, Berg #66169-015	(N)
NAD Data Network Input Connection:	female DB15 receptacle, Berg #66170-015	(O)
Power Connection:	circular, keyed, female, 4-contact, Switchcraft #SL-17-4F	(P)

POWER REQUIREMENTS

Input voltage: 9Vdc $\leq V_{IN} \leq$ 13Vdc
Power dissipation: 5.4 watts, max.

DISPLAYS

Percent Oxygen

Range: 0% O_2 to 100% O_2
Resolution: 1% O_2
Unit of Measure: % O_2
Accuracy: ±3% O_2

Low Oxygen Limit

Range: 18% O_2 to 99% O_2 OR (high limit setting -1), whichever is less
Resolution: 1% O_2
Unit of Measure: % O_2
Power-on Default: 30% O_2

High Oxygen Limit (displayed in low oxygen limit display when activated)

Range: 19% OR (low limit setting +1), whichever is more, to 100% O_2
Resolution: 1% O_2
Unit of Measure: % O_2
Power-on Default: 100% O_2

INDICATORS

100% Calibration Indicator	Green:	unit has been calibrated to 100% O_2
	Yellow:	unit is not calibrated
21% Calibration Indicator	Green:	unit has been calibrated to 21% O_2
	Yellow:	unit is not calibrated
Low Oxygen Indicator	Flashing Red:	low limit warning condition exists
Sensor Indicator	Green:	no sensor error
	Yellow:	sensor error condition exists
Self-Diagnostic Indicator	Green:	system operating
	Flashing Red & Green:	system failure

CONTROLS

Limit Decrement Control: Decrements low or high limit setting, whichever is currently displayed

Limit Increment Control: Increments low or high limit setting, whichever is currently displayed

NOTE: High limit setting is displayed in low oxygen limit display when limit decrement and increment controls are pressed simultaneously.

100% Calibration Control: Initiates calibration procedure for 100% O_2

21% Calibration Control: Initiates calibration procedure for 21% O_2

CONNECTIONS

Sensor Input Connection: Provides connection for sensor signal.
Power Input Connection: Provides connection for power from Narkomed 2A.
NAD Data Network Input Connection: Provides parallel data transfer from other North American Drager monitors.
NAD Data Network Output Connection: Provides parallel data transfer to other North American Drager monitors.

ALARMS

Low Oxygen Warning	If the measured oxygen concentration falls below the current low limit setting then: 1. the low oxygen limit is displayed intermittently with "LO" in the low oxygen limit display 2. the low oxygen indicator flashes red 3. a low frequency audible tone is produced
High Oxygen Caution	If the measured oxygen concentration rises above the current high limit setting then: 1. the high oxygen limit is displayed intermittently with "HI" in the low oxygen limit display 2. an intermittent audible tone is produced
Sensor Error Advisory	If either one of the two cells in the sensor becomes too weak or is not consistent with the other cell in the sensor, then the sensor indicator is lit yellow and a short audible tone is produced
Calibration Failure Advisory	If the unit fails to be calibrated within 3 minutes after power-on then: 1. both calibration indicators remain yellow 2. a short audible tone is produced
Uncalibrated Sensor Advisory	1. If the calculated oxygen percentage is greater than 103% O_2, then both calibration indicators are lit yellow 2. If the calculated oxygen percentage is greater than 105% O_2, then recalibration is forced
System Failure	If the system fails, then the self-diagnostic indicator flashes red and green intermittently

ENVIRONMENTAL

Storage	Temperature:	-40°C to 45°C	Humidity:	≤ 90% noncondensing
Operating	Temperature:	10°C to 45°C	Humidity:	≤ 90% noncondensing

SENSOR

PHYSICAL

Size: Diameter 40mm (1.575 in.) Length 45mm (1.77 in.)

Cord Length: Retracted 355.6mm (14 in.) Extended 1.5m (4 ft. 3 in.)

Electrical Connection: 9.5mm (.375 in.) dia., male, 3-contact plug Lemo #FGF0B.303.W0040

Gas Connections: 19.05mm (.750 in.) dia., friction fit with double o-ring seal

FUNCTION

Sensor Output: two galvanic cell anode signals each proportional to the concentration of oxygen using a common cathode reference. Signal voltage range decreases with sensor age from 100 mV full scale. A sensor is considered unusable when the full scale output signal is less than 45 mV.

ENVIRONMENTAL

Storage	Temperature:	$-10^{o}C$ to $40^{o}C$	Humidity:	$\leq$ 95% noncondensing
Operating	Temperature:	$15^{o}C$ to $40^{o}C$	Humidity:	$\leq$ 95% noncondensing

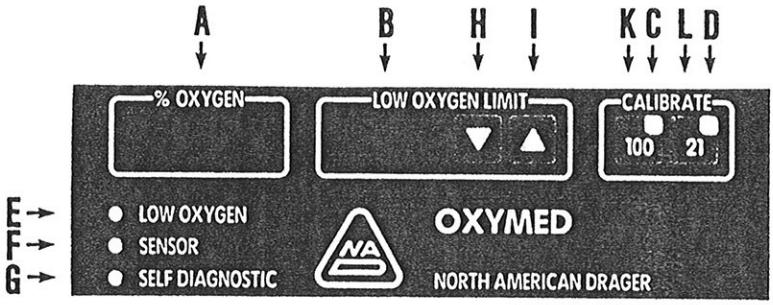

FIG 2

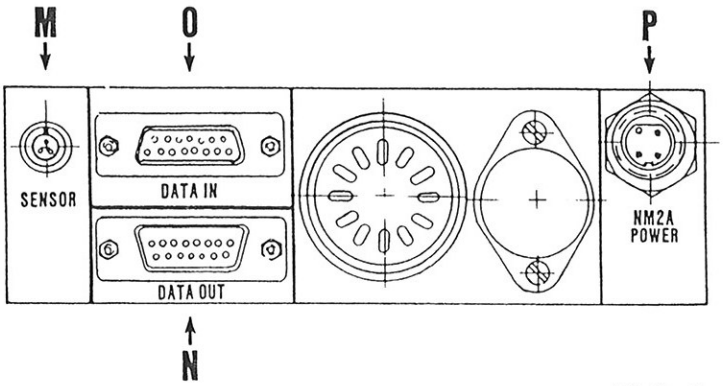

FIG 3