

TELEDYNE ELECTRONIC DEVICES

Design & Performance Specification

DESIGN & PERFORMANCE SPECIFICATION

OXYGEN MONITOR MODEL TED 60

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Design & Performance Specification

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OXYGEN MONITOR

Model: TED 60

1.0 INTRODUCTION

1.1 Scope

This document specifies a hand held oxygen monitoring system and accessories to monitor up to 100 percent oxygen concentration in medical gas mixtures.

1.2 General Description

The Oxygen Monitor utilizes two major functional components; a galvanic cell sensor, and an electronic signal processing unit. The current output from the sensor is fed into the electronic signal processor, where it is used to calculate the oxygen gas concentration and display it on the Liquid Crystal Display (LCD) screen. The data from the sensor is compared to values set by the user, and sets off the alarms if it exceeds those values.

1.3 Intended Use

The Monitoring System is designed to be used for verifying/monitoring oxygen concentrations in a variety of medical gas mixtures. The monitor is not recommended as primary monitoring device. The monitor may be used for verifying oxygen concentrations in gas mixtures used in:

□ Anesthesia
 □ Respiratory Therapy
 □ Neonatal Care
 □ Intensive Care

2.0 GENERAL SPECIFICATIONS

- 2.1 Physical
 - 2.1.1 Maximum Overall Dimensions

Height: 2.50 inches (cm.)
Width: 4.25 inches (cm.)
Depth: 1.25 inches (cm.)

2.1.2 Maximum Weight

< 9 Ounces (< 310 grams)

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- 2.1.3 Cable
 - 2.1.3.1 Retracted length:

1 foot

2.1.3.2 Extended length:

5 feet

2.1.4 Colors:

Case: Beige

- 2.2 Configuration
 - 2.2.1 System Power Requirement:

The unit will be fitted with 9 Volts - Alkaline battery

2.2.2 Battery Life:

Approximately 94 days continuous.

- 2.3 Environmental
 - 2.3.1 Temperature

a) operating: 0° to 40° C

b) storage:

 0° to 30° C, continuous

0° to 50° C, intermittent

- 2.3.2 Altitude
 - a) operating:

8,000 feet Maximum (2.4 Kilometers)

b) storage:

40,000 feet Maximum (12.2 Kilometers)

- 2.3.3 Relative Humidity
 - a) operating:

0 to 95 % non-condensing

b) storage:

0 to 99 % non-condensing

2.3.4 Cleaning and Disinfection

External surfaces will be able to be cleaned with alcohol or any medically approved disinfectant.

The reusable Tee Adapters will be able to be subjected to autoclaving procedures.

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The Oxygen Sensor is not designed to be cleaned or sterilized by hospital personnel.

3.0 PERFORMANCE REQUIREMENTS

- 3.1 Controls
 - 3.1.1 ON/OFF

The ON / OFF Key have the alternating effect of either turning the unit ON or OFF.

3.1.2 Calibrate

The Calibrate button located on top of the unit can be operated by pressing down on it and twisting. Rotate until the display reads 100%.

- 3.2 Display
 - 3.2.1 Numeric Display

A two display is active

- 3.3 Measurements and Accuracy
 - 3.3.1 Percent Oxygen Measurement:

Range of Sensor:

0 to 100 % Oxygen concentration

Accuracy

 \pm 2% of full scale (V/V) oxygen

at constant temperature.

Resolution

1 % (V/V) Oxygen

Response Time :

90% < 10 Seconds at 25 ° C

Stability

≥ 8 Hours of continuous use.

CONDITIONS:

3.3.1.1 Interfering gas and vapor:

Accuracy:

± 2% of full scale (V/V) oxygen.

List of Inhalation Anesthetic and Other Interfering

Gases/Vapors:

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- · Nitrous Oxide
- Halothane
- Enflurane
- Isoflurane

3.3.1.2 Cyclic pressure

Accuracy:

 \pm 2% of full scale (V/V) oxygen.

Response Time: 90% < 10 Seconds at 25 ° C

3.4 Calculations

3.4.1 Percent Oxygen

4.0 STANDARD ACCESSORIES

| | | Part Number | Quantity |
|-----|--------------------------|-------------|----------|
| 4.1 | Operator's Manual | M40575 | 1 |
| 4.2 | Sensor, Oxygen T-7 | A51327 | 1 |
| 4.3 | 9 Volts Alkaline Battery | B326 | 1 |
| 4.4 | Flow -Thru Adapter | B50057 | 1 |
| 4.5 | Cable Assembly | | 1 |
| 4.6 | Tee Adapter (22 mm) | A268 | 1 |

5.0 MAINTAINABILITY

- 5.1 Maintenance Requirements
 - 5.1.1 Battery
 - 5.1.2 Sensor
 - 5.1.3 Monitor

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6.0 GOVERNMENT AND OTHER AGENCY REQUIREMENTS

6.1 Food and Drug Administration (FDA)

This device shall comply with all applicable FDA regulations. This device shall comply with the Reviewer Guidelines for Respiratory Devices, February, 1993.

6.2 American Society for Testing and Materials (ASTM)

This device shall comply with all applicable ASTM, F1462 - 93, Specification for Oxygen Analyzers - Standards and where any noted exceptions are recorded on the Monitor's Qualification test reports.

6.3 International Organization for Standardization (ISO)

This device shall comply with all applicable ISO 7767, as stipulated Minimum Safety Requirements. Where any exceptions will be noted and recorded on the Monitor's Qualification test reports.

6.4 American National Standards Institute (ANSI)

This device shall voluntarily comply with applicable ANSI Standards.

6.5 International Electronics Commission (IEC)

This device shall voluntarily comply with IEC 601-1.

6.6 Canadian Standards Association (CSA)

This device shall be submitted for approval by CSA.

7.0 PACKAGING

7.1 Impact Resistance

When packaged for shipment the device shall withstand 10 consecutive drops of 30 inches on to a concrete surface in the worst possible condition without any structural or performance damage. (Reference: National Safe Transit Association, Project 1A).

7.2 Vibration Resistance

The packaged monitor shall be capable of withstanding a transport vibration for a total of 14,200 vibratory impact (0.60 inch displacement). (Reference: National Safe Transit Association, Project 1A).

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7.3 Spill Resistance

The monitor shall be devised to prevent entry of spilled materials which can cause malfunction or hazards to the unit.

7.4 Visual Acuity

All monitor annunciators display, overlays and control legends shall be readable and discernible from a minimum distance of three feet from the front panel at an illuminance of 215 lux.

8.0 INSTALLATION

8.1 Mounting

The monitor will be used as handheld unit.

9.0 APPENDIX

10.0 REFERENCE:

TED 60 Portable Oxygen Analyzer

Teledyne's Model TED 60 provides virtually instantaneous analysis and weighs only 8 oz.!

The TED 60 is a highly accurate and completely portable oxygen analyzer. Designed specifically for therapists and technicians, the TED 60 is ideal for checking oxygen in respirators, incubators, and other medical equipment.

The TED 60 has an "Instant On" capability which provides analysis within seconds after the unit is turned on. The instrument features Teledyne's patented* Polarographic Oxygen Sensor Class T-4. This maintenance-free long-life sensor provides accurate analysis ($\pm 2\%$), fast response time (90% in less than 6 seconds), and 12 months expected life.

The TED 60 measures just 4.3" H x 2.6" W x 1.3" D (110mm x 66mm x 33mm) so it's easy to handle. A sturdy clip makes for secure carrying on a belt or in a pocket.

FEATURES

- Fast response
- Compact size
- Lightweight
- LCD display with low battery indicator
- 24 month warranty (exc. sensor)
- Accurate, disposable Teledyne sensor (12 month warranty)

The unit is available with alternate sensors to meet your specific needs. Contact TED for additional information.

*U.S. Patent No. 4,077,861



SPECIFICATIONS

Range:

0-100% Oxygen

Accuracy:

±2% of full scale at constant

temperature

Response Time:

90% in less than 6 seconds at

77°F (25°C)

Operating

Temperature Range: 32-104°F (0-40°C)

Storage

Temperature Range: 32-122°F (0-50°C)

Power

Requirements:

One 9V battery

Expected

Battery Life:

12 months

Sensor Type:

T-4 Polarographic

Expected

Sensor Life:

12 months

Sensor Warranty:

12 months

Dimensions:

See Back

Weight:

7.9 Ounces (.23 Kg)

