TED 191 PORTABLE OXYGEN MONITOR INSTRUCTION MANUAL

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WARRANTY STATEMENT

The electronic control and display components of the TED 191 Portable Oxygen Monitor are warranted against defective workmanship and materials for 24 months from date of shipment from Teledyne.

The class T-7 Micro-Fuel Cell is warranted for one year from the date of shipment from Teledyne.

The liability of Teledyne, if any, shall be limited solely to the replacement and repair of the goods, and shall not include shipping costs or other incidental damages as defined in Section 2-715 of the U.S Uniform Commercial Code.

This warranty is null and void if any goods are subjected to misuse, negligence, accident or repairs other than those performed by Teledyne or an authorised service centre.

Caution: Federal Law restricts this device to sale by or on the order of a physician.



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INTRODUCTION

The TED 191 Portable Oxygen Monitor is an easy-to-use, portable instrument that provides fast and accurate oxygen monitoring and audio-visual alarm capability. The TED 191 is designed to monitor concentrations of up to 100% oxygen in medical gas mixtures.

The TED 191 Portable Oxygen Monitor is designed and manufactured in accordance with strict performance and quality protocols and subject to ISO 9002 Quality System protocols. When used correctly, this instrument will provide you with many years of trouble free service.

The TED 191 Portable Oxygen Monitor is a compact, self-contained unit, which is battery powered by four (4) dry cell batteries (size AA/penlight).



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APPLICATIONS

The instrument is designed for the measurement of oxygen concentrations in a variety of medical gas mixtures. It is recommended that the instrument **be used only as a secondary measuring device** to verify the concentration of oxygen in gas mixtures prepared using a gas blender or similar apparatus. The use of this monitor as a primary or only means of preparing gas mixtures is not advised.

The monitor is capable of verifying oxygen concentrations in gas mixtures used in:

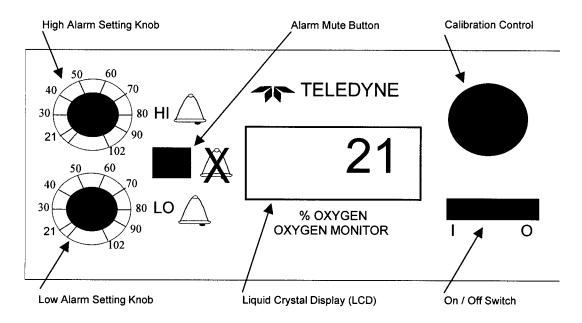
- Anaesthesia
- Neonatal Intensive care
- Adult Intensive care
- Respiratory / Oxygen Therapy

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DESCRIPTION OF FUNCTIONAL ZONES

FRONT PANEL



On / Off Switch

Allows the operator to turn the instrument on and off.

Alarm Mute Switch

Allows the operator to "mute" the sound of the audible alarm signal for \pm 60 seconds. During this time, a red signal lamp will flash, indicating a "muted" alarm condition is in force.

Calibration Control

Allows the operator to calibrate the instrument to one primary set point (usually 100%) in accordance with the designated calibration protocol. This protocol is defined further in this manual and also. Instructions in abbreviated form can be found on the top of the monitor casing.

High Alarm Setting

Allows the operator to define a high alarm threshold limit. Range 18% to 102% - if the actual measured value as displayed on the LCD exceeds this set threshold, an audible and visual alarm condition will be invoked.

Low alarm setting Knob

Allows the operator to define a low alarm threshold limit. Range 18% to 100% - if the actual measured value as displayed on the LCD falls below this set threshold, an audible and visual alarm condition will be invoked.

Liquid Crystal Display

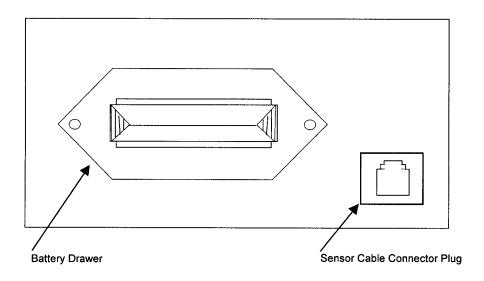
Displays measured oxygen concentration, low battery condition and provides a visual indication of either a high (+) or low (-) alarm threshold violation.



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DESCRIPTION OF FUNCTIONAL ZONES

REAR PANEL



Battery Drawer

The Battery Drawer contains 4 \times AA (Penlight) batteries required to power the instrument.

Sensor Cable Connector Plug

The Oxygen Sensor Connector Cable is plugged into this "one way" socket.

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SECTION ONE OPERATIONS

Note: Upon receipt, inspect the entire unit and accompanying accessories for damage or broken or loose parts. If damaged, do not use. Notify the Shipper, and consult Teledyne Electronic Technologies Sensor Technologies

1.1 **SET-UP**

To set-up your TED 191 Portable Oxygen Monitor :

1.1.1 Install the Batteries

See 1.2 below for procedure

1.1.2 Install the Sensor

See 1.3 below for procedure

1.1.3 Calibrate the Instrument

See 1.4 below for procedure

1.1.4 Normal Operation

See 1.5 below for procedure

1.1.5 Set the Alarms

See 1.6 below for procedure



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OPERATIONS

1.2 INSTALLING THE BATTERIES

Withdraw the battery drawer from the monitor casing, by grasping the side lugs located on either side of the battery drawer, and, firmly pinching them inwards, simultaneously pull the drawer outwards. When new, this action can be somewhat stiff and difficult to execute. Care should be taken not to damage either the drwaer or the casing of the monitor when executing this procedure.

Fresh batteries must be inserted into the four battery recepticles located within the battery drawer assembly. Care should be taken to ensure that the correct battery polarity is maintained.

Caution:

Improper installation of the batteries may result in heat damage to the

Re-insert the battery drawer into the monitor casing, and close.

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OPERATIONS

1.3 INSTALLING THE OXYGEN SENSOR

The T-7 Oxygen Sensor must be installed before the instrument can be used.

Ensure that the monitor is switched off.

Remove the sensor from its protective bag. Inspect the sensor for damage or electrolyte leakage. If the sensor is damaged obtain a replacement. Do not use the defective sensor as it may be damaged.

Caution: the sensor electrolyte is caustic. Do not let it come into contact with skin. If it does, immediately flush the affective area with water. Consult the Emergency first Ai procedures as set out in the Material Safety Data Sheet for the sensor. Do not attempt to open or repair the sensor. Leaking or exhausted sensors should be disposed of in accordance with local regulations. Consult the Material safety Data Sheet supplied with the sensor.

Plug one end of the coiled cable into the telephone jack receptacle on the end of the sensor. The jack will only fit one way, so if it does not fit, rotate it until it slides in easily.

Plug the other end of the coiled cable into the receptacle located on the right hand side of the rear panel of the instrument. This jack will only fit one way, so do not force it.

Note: For sterilisation procedures on the Oxygen Cell, see Section 3 on Page 15 below.

Caution : Do NOT autoclave the oxygen sensor



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1.4 CALIBRATE THE INSTRUMENT

Calibration should be effected at least once per shift, and always prior to the use of the instrument.

Note: Never expose the sensor to varying temperatures while calibrating (i.e never hold the sensor in your hand)

Ensure that the instrument is switched on, and that the oxygen sensor is connected to the instrument via the coiled cable. Expose the sensor tip to pure (100%) free flowing oxygen (a flow rate of approximately 6 to 8 litres per minute is recommended).

Tip: For best calibration results, use a T-adapter and flow diverter within a flow circuit, with the flow diverter attached to the sensor, allowing pure dry oxygen to flow past the sensor assembly.

Allow the displayed value to stabilise.

Pull out the Calibration Control Knob and rotate until the displayed value is stable at 100%. At this point, push the Calibration Control Knob back into its locked position.

Remove the sensor from the free flowing oxygen stream, and place it in standard ambient air (i.e. free from any extraneous oxygen concentration). Remove the flow diverter from the Sensor, if one was used during the calibration process, Observe that the displayed value falls to 21% (±2%). Calibration has been successful.

In the event that the displayed value does not reflect 21% ($\pm 2\%$), initiate a re-calibration (following the steps outlined above).

In the event that calibration is once more unsuccessful, check that the purity of the calibration gas being used is valid. If the quality of the oxygen being used in the calibration process is acceptable, and calibration is still impossible, replace the oxygen sensing cell.

If, after executing all the steps above, calibration is still not successful, return the instrument to Teledyne Electronic Technologies Sensor Technologies for repair.

Note:

The calibration process should always be executed in dry, non-humidified oxygen. Water vapour dilutes the oxygen concentration which can produce errors in the calibration. The accuracy of the instrument is only as good as the quality of the calibration process.

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1.5 NORMAL OPERATION

Switch the instrument on using the On-Off Switch.

Validate the calibration of the instrument by exposing the oxygen sensor to room air, and verifying that the display on the instrument reads 21% (\pm 2%). A further check can be carried out by exposing the sensor to a stream of 100% oxygen, and verifying that the display on the instrument reads 100% (\pm 2%).

Should this validation procedure indicate that the instrument is out of calibration, follow the calibration procedures set out in 1.4 above.

Once the calibration of the instrument has been verified, place the sensor tip within the stream of gas (e.g. breathing circuits) or the localised environment (e.g. incubators or oxygen tents) that requires to be monitored.

It is highly recommended that a flow diverter be used when monitoring a dynamic gas stream. This will prevent sample stagnation, and create a vortex effect that will facilitate a more accurate continuous assessment of the gas stream being monitored. The flow diverter should be plugged into a T-adapter, which must be located in line.

Note:

Check the breathing circuit for leaks. Ensure that the circuit downstream of the sensor does not produce any back-pressure or restrictions of the gas flow, or errors in the readings will result.

When using the instrument in a static environment, such as in an incubator, the flow diverter should be removed so that it does not interfere with the rapid exchange of gases through the gas permeable membrane of the sensor cell. When it is necessary to thread the cable through a small hole in order to gain access to the inside of the chamber, the instrument should be switched off, the cable should be disconnected at the sensor, threaded through the hole, and reconnected inside the chamber (see1.3 above), before commencing as described above.

Note:

Failure to remove the flow diverter will result in the marked slowing of the sensor response time.

The instrument will display the measured oxygen concentration. The high and low alarms should be set as detailed in 1.6 below.

When using the instrument in the presence of anaesthetic agents, it is possible for the measured value to reflect a fall. The magnitude of this fall is related to the level of oxygen concentration and the duration of the exposure to the anaesthetic agent. See 1.7 below for further details.



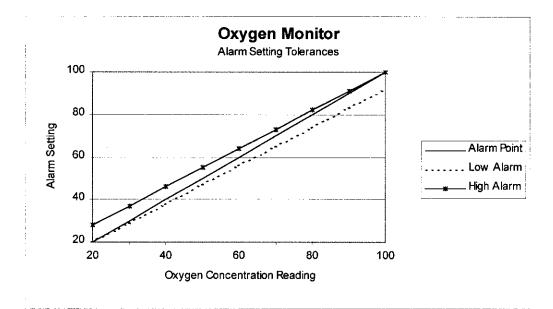
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1.6 SET THE ALARMS

The lines indicating the 100% graduations around the High and Low Alarm Settings Knobs are only intended as guides, and not as precise settings.

Once the desired oxygen concentration has been set, bring the high alarm setting down, by turning the High Alarm Setting Knob anti-clockwise, until the alarm is triggered, and then take the high alarm setting up by approximately 5%. Bring the low alarm setting up, by turning the Low Alarm Setting Knob clockwise, until the alarm is triggered, then take the setting down by approximately 5%. These settings will create a "window" of approximately 10%, within which the set oxygen concentration will now be measured. This window can be increased or decreased, according to the users requirements. Any deviation from this set window will trigger the alarm.

The graph alarm is accurate at 100% and within $\pm 8\%$ at 21%, and the low alarm is most accurate at 21%, and within $\pm 8\%$ at 100%. This is depicted in the graph below.



The instrument will alarm at any oxygen concentration below 18%.

In the event of a violation of the pre-set alarm limits, the instrument will provide both an audible and a visual alarm signal. Under these conditions, it is possible to "mute" or temporarily silence the audible alarm tone for about 60 seconds to allow corrective action to be taken. If the condition is not rectified within this time, then the audible alarm tone will be automatically reinstated. Audible alarm signals are tonally matched to the type of threshold violations i.e. low alarm violations are signalled via a lower pitched audible signal, while high alarm violations are signalled via a higher pitched audible signal.

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SECTION TWO

ANAESTHETIC AGENTS

The anaesthetic agents listed in the following table (Halothane, Enflurane, Isoflurane Sevoflurane, and Desflurane) were vaporised into a stream of 30%oxygen / 70% nitrous oxide. The resultant drops in displayed oxygen concentration after a 2 hour exposure period were observed. Exposurers in excess of 2 hours will provide marginally greater errors. The errors listed are typical for all gas permeable membrane oxygen sensors.

Exposure of the sensor to gas, free from any anaesthetic contamination, for a period of equal or greater than the exposure period, will eliminate the measurement error in most instances.

Gas or Vapor Level (Balance : Mixture of 30% O₂ / 70% N₂O, except where noted)

Gas or Vapor	Test Level	Oxygen Reading Error
Helium	50%, balance O₂	0%
Nitrous Oxide	80%, balance O ₂	0%
Carbon Dioxide	10%, balance O₂	0%
Halothane	4%	< -1.5% O ₂
Enflurane	5%	< -1.5% O ₂
Isoflurane	5%	< -1.5% O ₂
Sevoflurane	5%	< -1.5% O ₂
Desflurane	15%	< -1.5% O ₂

Errors are approximate and may vary based on exposure times and concentrations. These performances meet or exceed the requirements of ISO 7767: 1997 (E)

Caution:

The TED 191 Portable Oxygen Monitor should not be used in the presence of flammable anaesthetics such as diethal ether or cyclpropane.

The T-7 oxygen sensor should not be left in nitrous oxide mixtures any longer than absolutely necessary. After exposure to nitrous oxide mixtures, the sensor should be left in 100% oxygen overnight (e.g. left in a breathing circuit that has been flushed with pure oxygen). If the oxygen reading continues to drop after each use in nitrous oxide, the sensor should be removed from service. If the sensor can no longer be calibrated, or if there is any sign of electrolyte leakage, the sensor should be disposed of in accordance with local regulations and the specific guidelines as given in the Material Safety Data Sheet of the sensor.



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SECTION THREE

CLEANING AND STERILISATION

3.1 CLEANING THE TED 191 PORTABLE OXYGEN MONITOR

The instrument itself should be cleaned using a damp cloth. In the event of an excessive build-up of dirt, a mild alcohol solution (isopropyl) may be used to wipe over the instrument, which should be allowed to air-dry afterwards. In extreme cases, the monitor casing may be cleaned using a mild detergent.

Note:

The Accurox Oxygen monitor cannot be liquid sterilised or autoclaved -

irreparable damage may result.

3.2 STERILISING THE T-7 OXYGEN SENSOR AND CONNECTING CABLE

The T-7 oxygen sensors and connecting cables used on the instrument may be gas sterilised using low temperature ethylene oxide. A vacuum must **not** be drawn on the sensor during the sterilisation process.

SECTION FOUR

Do's AND DON'TS

Do's

- Read the Operators Manual thoroughly before using the instrument.
- ☑ Calibrate once per shift, and prior to each and every use.
- Check the high and low alarm threshold settings prior to use.
- ☑ Replace the batteries immediately when required.
- ☑ Keep the instrument, cable and sensor dry at all times.
- ☑ Re-calibrate after changing the sensor or batteries.
- Visually inspect the whole instrument prior to use.
- ☑ Check the integrity of all cable connections routinely.
- Remove and carefully store the "flow diverter" when using the instrument in "static" environments such as incubators, oxygen hoods etc.
- ☑ Perform an alarm functionality test prior to each use.
- Remove batteries if the instrument is not to be used for a month plus

DON'TS

- Use the Accurox Oxygen Monitor if you suspect any malfunction.
- Use the monitor in the presence of flammable anaesthetics.
- Autoclave the instrument and/or the sensor.
- Submerge the instrument and/or sensor in water or any other liquid.
- Expose instrument to other equipment with high levels of RFI emission.
- Place the instrument itself in a water vapour saturated environment.
- Expose the LCD to excessive direct sunlight
- Dispose of the sensor cell in fire, or place in an incinerator.

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5.1 ROUTINE VISUAL INSPECTION

Always inspect the instrument prior to use for obvious damage or for parts or components missing. Make a point of checking the oxygen sensor cell for signs of electrolyte leakage, water condensation on the sensing surface. Also check the integrity of the cable and all cable connections.

5.2 CHANGING BATTERIES

From time to time the 4 x AA (penlight) dry cell batteries that power the instrument will require replacement. This requirement will be indicated via a "LO BAT" alarm message located in the top left hand corner of the LCD display. It is also possible, if the instrument has not been used for sometime, that the batteries will be depleted to the extent that the instrument will not power up when switched on. In both instances, the batteries must be replaced.

To change the batteries, follow the procedures set out in 1.2 above.

Initiate a calibration once the new batteries are installed prior to using the instrument.

5.3 CHANGING THE OXYGEN SENSOR CELL

From time-to-time the oxygen sensor cell, being a consumptive electro-chemical device, will require replacement. This requirement will be indicated via an inability to achieve calibration i.e the range provided by the Calibration Control Knob will not be sufficient to achieve the setting of 100% on the LCD display when exposing the sensor tip to 100% pure oxygen.

To change the oxygen sensor, follow the procedures set out in 1.3 above.

Initiate a calibration once the new sensor has been installed prior to using the instrument.

A Sensor Cell Replacement Log has been provided for the reference of the users, and is located at the back of this Instruction Manual. The details of the replacement sensor should be entered into this log at the time of changing.

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SECTION SIX

TROUBLESHOOTING

SYMPTOM	CURE / REMARK
	Check battery drawer is properly located.
No numeric display on	2) Check battery polarity .
the LCD when powered on	3) Check batteries for replacement
	4) External power : check polarity and voltage of supply; : check if functional on batteries.
	Check calibration process (as described above).
	2) Check flow rate of calibrating gas (6 – 8 lpm)
	3) Check sensor cell connection.
	4) Check sensor cable connection.
Inability to achieve calibration	5) Check quality of calibration gas.
	6) Check that the calibration gas is dry (not humidified).
	7) Wait for 1 or 2 minutes, then attempt a re-calibration.
	8) Check sensor cell for damage or electrolyte leaks.
	9) Return monitor to authorised service agent for repair.
Constant non-mutable alarm condition	Check high and low alarm settings for possible "crossed" settings i.e. high threshold value is set lower than low threshold value.
Drift is displayed	Do not hold the sensor whilst calibrating, as the warmth from your hand may cause the ambient temperature compensation circuit to activate, resulting in unstable displayed values.
readings whilst calibrating or	2) Try calibrating a known "good" sensor.
immediately thereafter	3) Repeat calibration.
	4) Replace the sensor cell.
There is no reaction to changes in oxygen concentration	Remove the sensor tip from the T-adaptor, unscrew the "flow diverter" and gently swab any excess moisture off the sensor cell membrane, then flow dry gas over the membrane.



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TROUBLESHOOTING

SYMPTOM	CURE / REMARK
The displayed readings	Remove the sensor tip from the T-adaptor, unscrew the "flow diverter" and gently swab any excess moisture off the sensor cell membrane, then flow dry gas over the membrane.
are unstable	Check for a source of RFI emission. Relocate the instrument.
	3) Check that the calibration control knob is properly loced in position.
Instrument reads "00"	The sensor is not plugged in.
mstament reads 55	There is bad sensor/cable or cable/monitor connection.
Displayed value drifts by 2 – 3% over 3 – 4	Replace sensor cable.
hours	2) Replace cable.
Alarm continuously activates when displayed value is less than 18%	The minimum low alarm threshold is 18%. The Teledyne TED 191 will always alarm under these conditions.

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SECTION SEVEN

TECHNICAL SPECIFICATIONS

SAFETY CLASSIFICATION	Complies to IEC 601 – Safety of Medical Equipment Internally powered equipment Drip proof – IPX 1 Not suitable for used with flammable anaesthetic mixture
POWER	Internal : DC 6V, 4 dry cell batteries – size AA/penlight
MASS	525 grams (with T-7 oxygen sensor)
DIMENSIONS	59mm (H) x 152mm (W) x 115mm (D)
BATTERY DURATION	Approximately 900 hours of continuous non-alarming operation Low battery status indication is provided Replace batteries within 48 hours of low battery indication
ALARMS	High oxygen concentration (18% to 102%) Low oxygen concentration (18% to 100%) Low battery (visual alarm only) Most alarm conditions are signalled audibly and visually, with a 60 second audible alarm mute facility provided
MEASUREMENT RANGE	0 to 100% of localised environmental oxygen concentration
DISPLAY TYPE	Liquid Crystal Display (LCD)
SENSOR TYPE	Class T-7 (Galvanic)
ACCURACY	Approximately 2% linear
SENSOR LIFE	Approximately 12 months in most applications



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