User Manual

OxyLite™

Continuous *in vivo* and *in vitro* combined pO_2 and temperature monitoring

Product Documentation and User Manual

Revision 1.1

Designed and Manufactured by:

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1. SAFETY INFORMATION

This section contains important safety information related to the general use of the OxyLite monitor. Other important safety information appears throughout this manual in the form of warnings and cautions.

1.1 Intended Use

The OxyLite monitor is intended for the continuous measurement of pO_2 and temperature in tissue (i.e. *in vivo*), physiological fluids, cell cultures or other samples (i.e. *in vitro*).

OxyLite is suited to the determination of tissue or cell culture hypoxia as the measurement technique is particularly sensitive at low tissue pO_2.

OxyLite may be used in conjunction with OxyFlo, a laser Doppler blood flow monitor that is intended for monitoring microvascular blood perfusion in tissue. The combination of these two fibre optic measurement systems provides simultaneous tissue blood flow and oxygenation data. Combined sensors are available that support simultaneous pO_2 and blood perfusion monitoring.

OxyLite is not suited to the measurement of pO_2 values in excess of 200mmHg or in non-aqueous environments.

1.2 Contra-Indications

OxyLite is purely for laboratory, industrial and research use and is NOT a medical device. OxyLite does NOT possess requisite regulatory approval(s) for use with human subjects or patients.

1.3 FCC Compliance

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause interference, in which case the user will be required to correct the interference at his/her own expense.

1.4 EMC Compliance – EC Declaration of Conformity

This equipment meets intent of Directive 2004/108/EC for Electromagnetic Compatibility. Compliance was demonstrated to the following specifications as listed in the Official Journal of the European Communities.

EN 61326-1:2006

EN 61326-2-1:2006

1.5 OxyLite Symbols

SN	Serial number	REF	Catalogue number (product code)
	Date of manufacture		Equipment should not be disposed of in the normal waste stream
	Attention. See instructions for use.		Read instructions for use
	USB output		Analogue outputs

Table 1: OxyLite symbols

1.6 Definitions

 **WARNING**	A warning indicates the possibility of injury to the operator.
 **CAUTION**	A caution indicates a condition that may lead to equipment damage and/or malfunction.

1.7 Summary of Warnings for the OxyLite Monitor

 WARNING	Do not attempt to open the OxyLite. There are no user-serviceable parts inside. There is a risk of electrical shock or other injury or permanent damage to the monitor.
 WARNING	The OxyLite should only be repaired or serviced by Oxford Optronix Ltd. trained service staff.
 WARNING	To avoid the risk of electric shock or shorts, do not spray, pour or spill any liquid in or on the OxyLite.

1.8 Summary of Cautions for the OxyLite Monitor

 CAUTION	DO NOT attempt to operate the OxyLite in the vicinity of imaging or therapeutic equipment that emits ionising radiation or produces a strong magnetic field as the performance of the monitor may be affected.
 CAUTION	DO NOT attempt to autoclave, pressure sterilise, or expose to radiation, any part of the monitor.
 CAUTION	Use only sensors, cables and accessories supplied by Oxford Optronix Ltd.
 CAUTION	Failure to pack the OxyLite monitor appropriately for repair or service may result in potentially costly damage to the monitor during transit.

1.9 Summary of Cautions for OxyLite Sensors

 CAUTION	OxyLite sensors should be HANDLED WITH CARE. Failure to do so may result in breakage of the internal optical fibre, loss of the oxygen sensing tip or separation of the cable from the sensor connector. REFER TO WARRANTY STATEMENTS PROVIDED AT THE END OF THIS DOCUMENT.
 CAUTION	OxyLite sensors are NOT approved for use on patients.

 **CAUTION**	The tips of oxygen sensors are fragile and can be damaged by attempts to clean them without due care and attention.
 **CAUTION**	For safe storage of OxyLite sensors always refit the protective black cover when a sensor is not in use.
 **CAUTION**	DO NOT drop, stretch or ‘kink’ any part of an OxyLite sensor. Permanent damage may result.
 **CAUTION**	Attempting to disconnect the sensor by pulling the cable sleeving instead of the front of the sensor connector may cause irreparable damage to the sensor.
 **CAUTION**	DO NOT soak or immerse OxyLite sensors in corrosive solution. Permanent damage may result.
 **CAUTION**	DO NOT store OxyLite sensors in bright sunlight.
 **CAUTION**	AVOID using OxyLite sensors under strong (e.g. surgical) lights.
 **CAUTION**	The oxygen-sensitive tip of sensors must be isolated from atmospheric oxygen to ensure reliable *in situ* oxygen measurements.
 **CAUTION**	Oxygen sensor calibration accuracy is warranted for a period of 6 months from factory calibration.
 **CAUTION**	If the sensor connector has been immersed in 70% alcohol ensure that it is completely free of pockets of non-evaporated alcohol prior to use.
 **CAUTION**	The effect of exposure to heat, radiation, glutaraldehyde, ETO gas or plasma on the performance and measurement accuracy of OxyLite sensors has not been validated.

2. INTRODUCTION

2.1 General Description

The OxyLite is an instrument capable of continuous, quantitative measurement of the partial pressure of oxygen (pO_2) and temperature in tissues, physiological fluids, cell cultures and other *in vitro* applications. pO_2 is also variously referred to as an 'oxygen tension' or as 'dissolved oxygen'.

OxyLite is an optical device based upon the principle that the presence of molecular dissolved oxygen in tissues or fluids can terminate (quench) light emitted by a fluorescent compound (dye). The quenching of the fluorescent light is proportional to the pO_2 in the vicinity of the dye.

The OxyLite system consists of a portable monitor and detachable, re-usable sensors. The monitor houses a green LED light source, sensitive photo-detector, a PC module and proprietary signal processing electronics. All OxyLite sensors comprise a single optical fibre that conducts light from the monitor to the sensing tip. The sensing tip contains a platinum-based fluorescent dye held within a polymer matrix.

When the dye is illuminated/excited with light from the monitor, it fluoresces. The fluorescent light is returned to the monitor using the same optical fibre and the signal processor determines the fluorescent decay time. From this, the corresponding pO_2 is derived. As pO_2 in the vicinity of the sensing tip decreases, the extent of quenching decreases and the fluorescence decay time increases. The quenching process is a purely collisional dynamic where the energy from the excited fluorescent dye is transferred to the oxygen molecule during a collision, hence, reducing the emission intensity as well as the fluorescent lifetime of the dye. Thus, the oxygen content of the tissue or fluid under investigation is not changed by the measurement process.

Measured pO_2 is displayed on the monitor's display in units of either millimetres of mercury (mmHg) or kilo Pascal (kPa).

Measured pO_2 is dependent on the local temperature at the sensing tip. In general it is therefore important that pO_2 measurements are compensated for temperature. To this end, the OxyLite monitor incorporates a calibrated temperature measurement system. The OxyLite monitor performs automatic temperature compensation and will generate a continuous readout of temperature when a combined oxygen/temperature sensor is in use.

In order to display an accurate pO_2 value the OxyLite requires calibration data. The calibration data is sensor-specific and for maximum ease of use each sensor is supplied pre-calibrated. The calibration data, as well as setup information are contained in a miniature 'EEPROM' electronic chip integral

to the sensor connector; these data are automatically read by and transferred to the OxyLite monitor upon connection.

Available OxyLite functionality is controlled via a functions button at the rear of the monitor.

Continuous pO_2 and temperature data from the OxyLite can be acquired for recording, playback and analysis using a suitable data acquisition system connected via a choice of interfaces at the rear of the monitor.

2.2 List of Key Features

- Absolute units of dissolved oxygen
  The fluorescence-based technique employed by the OxyLite type monitors provides an absolute measurement of dissolved oxygen in mmHg or kPa. For *in vivo* applications, this provides a direct readout of oxygen availability to cells and tissue, in contrast to blood oxygen saturation assessment (pulse oximetry), which merely describes the haemoglobin oxygenation status of blood.
- Sensitivity and accuracy
  Third-generation opto-electronics provide unmatched sensitivity, stability and accuracy in the physiologically relevant pO_2 range (0 - 200mmHg) and under conditions of hypoxia (0 – 15mmHg).
- No oxygen consumption
  Zero oxygen consumption at the point of measurement, thus innately suitable for continuous and absolute oxygen sensing, even under conditions of extreme hypoxia.
- Microchip sensors
  'EEPROM' technology embedded within our purpose-designed connectors provides unsurpassed ease of use and user convenience by completely eliminating all calibration procedures. Simply 'plug-in and go'.
- OLED display
  High-contrast, 40-character, 140º viewing-angle OLED display.
- Built-in temperature compensation
  Automatic temperature compensation of the pO_2 measurement through optional, integrated temperature sensors.
- Versatility
  Full support for both *in vivo* (tissue) pO_2 applications AND measurement of dissolved oxygen *in vitro* (e.g. hypoxic cell culture, tissue constructs, bioreactors and more).

- Minimally invasive for *in vivo* applications
  Oxygen sensor diameters range from approximately 230µm - 750µm to suit a host of tissue monitoring applications and cause minimal tissue disruption in use.
- MRI compatible sensors
  Dedicated 8m sensors provide support and compatibility for magnetic resonance imaging.
- Single-sensor multi-parameter monitoring
  Our OxyLite oxygen and temperature monitor is designed specifically to be used in tandem with our OxyFlo blood flow monitor, providing support for simultaneous measurements of tissue oxygenation, blood flow and temperature using dedicated combined sensors.
- USB digital output
  A dedicated USB output supports direct streaming of recordings to a PC running the popular LabChart® Pro charting software. Features automatic identification of the monitor and pre-loading of configuration and channel settings for 'plug and play' convenience.
- Analogue outputs
  Continuous data recording to PC or Mac platforms is also supported via standard analogue data outputs offering compatibility with third party data recording solutions.
- 2-year product warranty
  OxyLite is supplied with a comprehensive 2-year manufacturer's warranty, covering defects in material or in workmanship.

2.3 The OxyLite Monitor

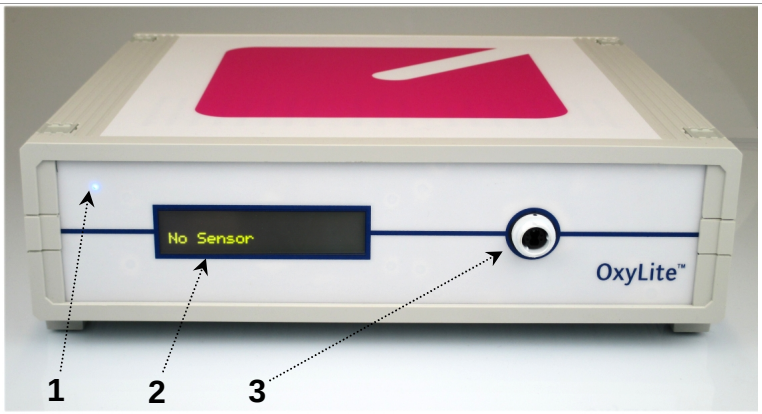


Figure 1: Front view of the OxyLite

1. Power-on indicator light
2. Alphanumeric OLED display
3. Sensor connector

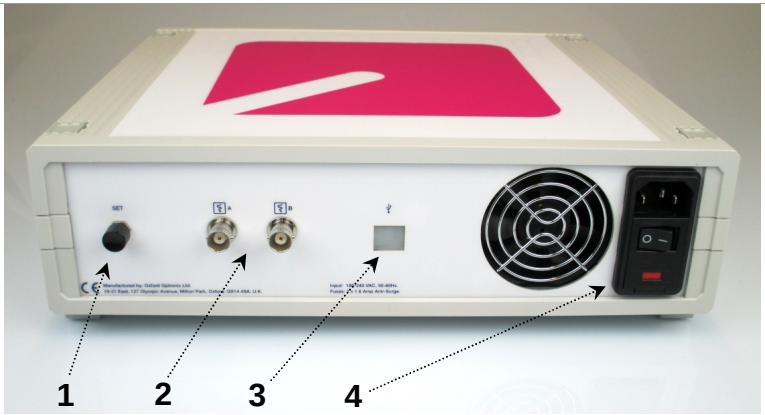


Figure 2: Rear view of the OxyLite

1. SET button (see section 3.6)
2. BNC analogue output connectors. A = 'Oxygen (pO_2)'; B = 'Temperature'
3. USB serial output for optional *direct* data streaming to LabChart® Pro
4. IEC mains inlet (containing fuses) and on/off switch

2.4 OxyLite Sensors

Introduction

A range of pO_2 sensors are available for use with the OxyLite monitor. In addition, there are sensors available for the simultaneous measurement of microvascular blood perfusion when OxyLite is used in conjunction with its counterpart, the OxyFlo.

All OxyLite sensors comprise a 230µm diameter bare optical fibre, which is used to direct light to and from the sensing tip. The fibres terminate at one end of the sensor in the sensing tip (protected beneath a removable black tubular protective cover) and at the other end in a connector plug that attaches to the OxyLite. The connector plug is colour-coded with a **blue** band.

A durable white polyurethane sleeving serves to protect the optical fibre(s) along the 2.5m length of the sensor.

The oxygen sensing tip comprises a platinum-based dye held within a matrix of silicone. A polymer layer encapsulates the tip and the fibre, giving an overall tip diameter of approximately 250µm (bare-fibre sensors only).

Since measured pO_2 is dependent on the local tissue temperature, some OxyLite oxygen sensors are available with integrated temperature sensors. These monitor temperature from the site of oxygen measurement and provide automatic temperature compensation of the oxygen measurement. The temperature sensors are polyurethane-coated T-type thermocouples that have a diameter of approx. 100µm.

A comprehensive list and detailed description of available sensor types can be found on our website (www.oxford-optronix.com).

The number of plugs on a sensor is dependent on the number of parameters being measured. Oxygen and dual-parameter oxygen/temperature sensors feature a single plug, while triple-parameter sensors, also incorporating laser Doppler blood flow support feature two connector plugs. The optional temperature parameter is supported by additional pins integral to the oxygen connector plug, i.e. no additional connector plug is required.

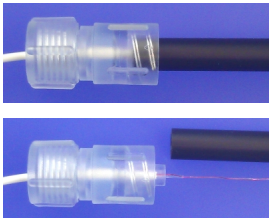
In the case of combined sensors the connector plug carrying the laser Doppler signal is colour-coded with a **red** band.

Sensor presentation

OxyLite sensors consist of an optical fibre used to direct light to and from the sensing tip.

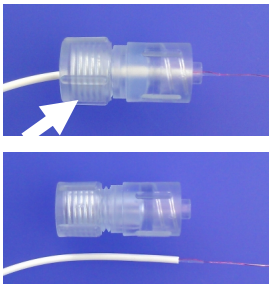
The fibres terminate at one end in the sensing tip (protected beneath a black protective cover) and at the other end in a connector plug that attaches to the OxyLite.

A durable white polyurethane sleeving serves to protect the optical fibre(s) along the 2.5m length of the sensor.



The removable protective cover is push-fitted into the Tuohy Borst / Luer adapter.

The protective cover serves to protect the delicate optical fibres and should be refitted following sensor use and for sensor storage.



The Tuohy Borst / Luer adapter is intended to accommodate the protective cover (above) and can also serve to accept a catheter or needle introducer (refer to section 3.8 below).

The adapter grips the white sensor sleeving internally but can itself be removed by twisting the threaded rear section of the adapter (arrow) in an *anticlockwise* direction.

NOTE: When replacing the adapter and in order to achieve a secure ‘grip’ on the sleeving, ensure that the threaded rear section is twisted tightly.

Figure 3: An OxyLite sensor (‘NX-BF/OT’ type depicted)

Sensor calibration

All OxyLite sensors are individually factory pre-calibrated prior to dispatch. Sensor calibration data is stored within integrated 'EEPROM' electronic chips to provide true 'plug and play' convenience. The electronic chip contains detailed, sensor-specific calibration information which is read and loaded automatically by the monitor upon connection.

Each sensor is uniquely identified with an alphanumeric code of the following general format 'XXnnnX', for example 'MR007S'.

The sensor ID is printed at the connector (plug) end of each sensor and is also found on the sensor packaging.

It is not possible for the user to calibrate OxyLite sensors.

 CAUTION	OxyLite sensors should be HANDLED WITH CARE. Failure to do so may result in breakage of the internal optical fibre, loss of the oxygen sensing tip or separation of the cable from the sensor connector. REFER TO WARRANTY STATEMENTS PROVIDED AT THE END OF THIS DOCUMENT.
 CAUTION	OxyLite sensors are NOT approved for use on patients.
 CAUTION	DO NOT drop, stretch or 'kink' any part of an OxyLite sensor. Permanent damage may result.
 CAUTION	Attempting to disconnect the sensor by pulling the cable sleeving instead of the front of the sensor connector may cause irreparable damage to the sensor.
 CAUTION	DO NOT soak or immerse OxyLite sensors in any corrosive solution. Permanent damage may result.
 CAUTION	DO NOT store OxyLite sensors in bright sunlight.
 CAUTION	AVOID using OxyLite sensors under strong (e.g. surgical) lights.

CAUTION

For safe storage of OxyLite sensors always refit the protective black cover when a sensor is not in use.

2.5 Accessories

The following, non sensor-related accessories are available from Oxford Optronix Ltd. for use with the OxyLite:

Product Code	Product Description
OLO-BNC	BNC data cables for OxyLite or OxyFlo. Pack of 2 (1 m)
LABCHART_PRO	LabChart® Pro software (PC/Windows® only), incl. 1 user license and 5 years free updates
VALUE ADC	12 channel analogue output data recorder and PC software, by Dataq Inc.
POWERLAB	A range of analogue output data recorders and associated PC or Mac software, by AD Instruments

Table 2: Optional accessories for OxyLite

3. MONITOR SETUP AND USE

3.1 Unpacking and Inspection

Immediately notify Oxford Optronix Ltd. or your local distributor if the outer packaging or carton is wet or damaged in any way. Unpack the OxyLite and its components, ensuring that all items listed on the enclosed packing list / dispatch note are present. If anything is missing or damaged please contact Oxford Optronix Ltd. or your local distributor.

NOTE: We recommend that the original shipping carton and shock-absorbing inserts be stored in a safe place rather than discarded, since these will be required for any warranty returns and/or for shipping the OxyLite safely for scheduled servicing.

3.2 List of Standard Components

- OxyLite monitor
- Country-specific IEC power cable
- User Manual (this document)

3.3 Connecting and Powering-up the Monitor

1. Position the unit on a flat and stable surface. Note that the standard sensor cable length is 2.5 metres (approx. 8 feet).
2. Ensure that the power On/Off switch at the rear of the OxyLite is in the OFF (0) position.
3. Plug the IEC power cable into the IEC mains inlet at the rear of the OxyLite and the plug end of the IEC power cable into a wall mains supply.
4. Power up the monitor via the power On/Off switch at the rear of the OxyLite. The monitor will automatically detect the mains voltage (110 - 240V supported). The power-on indicator LED will illuminate and the monitor will run its internal boot sequence and start-up checks (approx. 20 seconds in total).

   During this time there will be several audible ‘beeps’ and the display will show a number of messages (see section 3.5) including confirmation of internal software version and the date/time.
5. Once the display shows ‘No Sensor’ the monitor is ready for sensor connection and use (see section 3.4).

3.4 Connecting / Disconnecting Sensors

The OxyLite supports pre-calibrated sensors featuring integrated 'EEPROM' electronic chips to provide true plug and play convenience. The electronic chip contains sensor-specific calibration information which is read and loaded by the monitor upon connection.

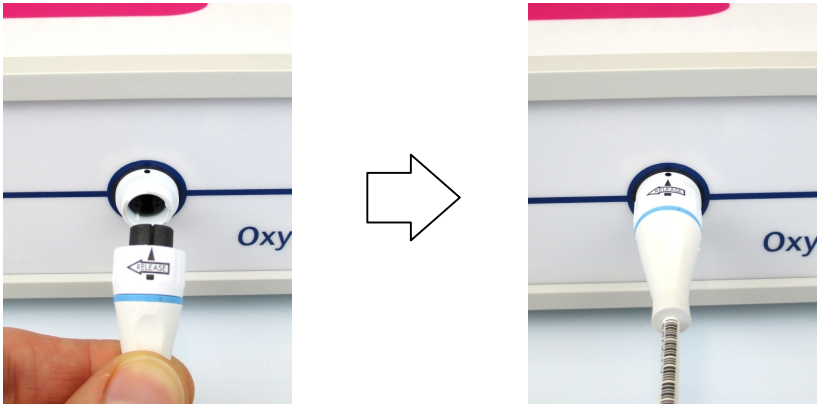


Figure 4: Connecting and disconnecting a sensor

Align the sensor connector such that the arrow is aligned with the black dot on the instrument connector surround and simply push. The connector will snap into position and calibration and other sensor information will be read automatically by the monitor.

Disconnect by twisting the front portion of the sensor connector anti-clockwise in the direction of the 'Release' arrow printed on the connector.

CAUTION

Attempting to disconnect the sensor by pulling the cable sleeving instead of the front of the sensor connector may cause irreparable damage to the sensor.

3.5 Display Messages

The OxyLite front panel displays the pO_2 and temperature measurements when a sensor is connected and in use. Other messages, including error messages are also displayed to the user. A list of messages and their meaning is provided below:

Message	Description
Oxford Optronix	First message that is displayed during the OxyLite boot sequence. Analogue output during this time is 2.5V (50% scale).
OxyLite pO2_Soft 2.04	Second message displayed during the boot sequence. Confirms instrument model and internal software version. Analogue output during this time is 2.5V (50% scale).
Date dd/mm/yy Time hh:mm	Third message of the boot sequence. Displays (factory set) date and time (GMT). Analogue output during this time is 0V (0% scale).
No Sensor	There is no sensor connected to the OxyLite but the monitor has completed its boot sequence and is ready for use. Analogue output during this time is -2.5V (-50% scale).
Loading SensorID XXnnnX	First message displayed after a sensor is connected. Confirms the sensor 6-digit ID in the format XXnnnX, where X is a letter and n is a number.
Use Left nn hrs Cal.Expiry dd/mm/yy	Second message after a sensor is connected. Confirms hours of accumulated longevity remaining and the calibration period expiry date (see section 3.7). If either limit has been exceeded, press the SET button to clear (see section 3.6).

nnn.nmmHg nn.nºC	Normal display with a sensor connected, showing real-time pO_2 and temperature measurements.
Select Setting Units mmHg	Pressing the SET button when no sensor is connected allows the user to choose between mmHg and kPa units for pO_2. The selection is remembered when the monitor is powered down.
Select Setting Set Temp. nn ºC	Pressing the SET button when an oxygen-only sensor is connected allows the user to select the desired manual compensation temperature. Press and hold to scroll. The chosen temperature is lost when the monitor is powered down.
XXnnnX Sensor Expired (3)	Error message displayed when a sensor reaches the end of its Accumulated Longevity grace period (see section 3.7).
XXnnnX Sensor Expired (1)	Error message displayed when a sensor reaches the end of its Shelf Life (see section 3.7).
XXnnnX Sensor Error (nnn)	Indicates a recognized error condition. Refer to section 5.1 and table 6.
XXnnnX Sensor Fault (nnn)	Indicates a potential sensor hardware condition.
Device Fault (nnn)	Indicates a potential device hardware condition.

Table 3: OxyLite display messages

3.6 The SET button

OxyLite functionality is controlled via a SET button at the rear of the monitor (see figure 2).

Pressing the button when no sensor is connected allows the oxygen units to be selected from a choice of mmHg or kPa.

Pressing the button when a sensor is connected allows the user to toggle through the supported temperature range in order to manually set the compensation temperature (see section 3.9 for a dedicated description of temperature compensation functionality).

This function is supported ONLY when a single-parameter (oxygen-only) sensor is connected. Combined oxygen/temperature sensors will read temperature continuously and in real time.

NOTE: Press and hold the button to scroll through the available temperature range.

The SET button is also used to clear the '`Use Left | Cal.Expiry`' message. See section 3.7 below.

3.7 Sensor Shelf Life and Accumulated Longevity

The usable lifetime of all oxygen sensors is defined by,

- a warranted calibration period (6 months),
- a total used or unused shelf life limit (2 years),
- a maximum accumulated usage limit (48 hours at default sampling rate).

Calibration Period and Total Shelf Life

Oxygen sensors are provided with a 2-year shelf life.

Total shelf life is defined as the time from factory calibration until sensor expiry and is independent of sensor usage. The OxyLite will not accept a sensor that has exceeded its 2-year shelf life.

Oxford Optronix warrants the **calibration accuracy** of OxyLite sensors for the first 6 months of the 2-year shelf life (refer to Sensor Warranty statement towards the end of this document).

The 6 month point is referred to as the 'Recommended use-by date' and is printed on the sensor packaging and cited as the '`Cal.Expiry`' date on the OxyLite display when a sensor is connected.

When the 6-month calibration period expires the instrument will display the '`Use Left | Cal.Expiry`' warning message. This can be cleared by pressing the SET button at the rear of the monitor, which will allow measurements to continue.

The use of sensors beyond the 6-month calibration period is entirely at the discretion and at the own risk of the user.

NOTE: When a sensor with an expired calibration is connected, the OxyLite display will maintain the '`Use Left | Cal.Expiry`' message until the user presses the SET button at the rear of the monitor.

The maximum delay between factory calibration and sensor delivery will typically be 2 weeks. Thus, the warranted calibration period from *receipt* of a sensor may be slightly short than 6 months.

The 2-year shelf life and the 6-month warranted calibration period should be considered when establishing sensor inventories.

Accumulated Longevity

Sensor longevity is also limited by usage, an effect that relates to the total (accumulated) time that the sensor has been 'exposed' to the light source within the instrument.

The total (accumulated) time before a sensor expires is **48 hours**. This excludes a 2-hour 'grace' period.

The accumulated longevity status of a sensor is briefly displayed as hours remaining upon sensor connection ('`Use Left`').

Upon reaching an accumulated usage of 48 hours the instrument will display the '`Use Left | Cal.Expiry`' warning message. This can be cleared by pressing the SET button at the rear of the monitor. Measurements can then continue until the 2-hour 'grace' period has been exhausted.

At approximately 50 hours of accumulated usage the monitor will reject the sensor and the measurement will cease.

NOTE: When a sensor with an exhausted accumulated longevity period is connected the OxyLite display will maintain the '`Use Left | Cal.Expiry`' message until the user presses the SET button at the rear of the monitor (see section 3.6). If the 2-hour 'grace' period has not been exhausted, measurements will continue.

IN SUMMARY:

- Oxygen sensors have a maximum used or unused shelf life of 2 years from factory calibration.
- Oxygen sensor calibration accuracy is warranted for a period of 6 months from factory calibration.
- Oxygen sensors have a maximum accumulated longevity of 48 hours (excluding a 2 hour 'grace' usage).
- Oxygen sensors will expire due to shelf life expiry OR due to the accumulated longevity limit, whichever occurs first.

3.8 Placement of Sensors in Vivo or in Vitro

Please note that detailed guidelines for the use of sensors in a variety of tissue monitoring applications are maintained on our dedicated support site:

http://www.oxford-optronix.com/support/supp_oxylite.htm

In summary:

Depending on sensor type, the oxygen-sensitive region is located either at the very tip ('bare-fibre' sensors), or slightly posterior to the tip ('NP/O' and 'LAS' sensor types).

CAUTION

The oxygen-sensitive region of sensors must be isolated from atmospheric oxygen to ensure reliable *in situ* oxygen measurements.

For *in vitro* environments (e.g. cell culture) the placement of sensors generally simply requires the direct exposure of the sensor tip to the fluid of interest. Brief measurements can be carried out by hand; a miniature clamping apparatus or any other type of jig can be used for longer term measurements.

The optimum approach for introducing sensors into biological tissues (*in vivo* use) will depend on the sensor type, the tissue to be studied, the size of the animal model, the nature of the application and the personal preferences of the user. In general we recommend the use of suitable catheter introducers as the majority of sensor types are insufficiently robust for direct tissue insertion.

3.9 Temperature Compensation

The luminescence-based oxygen monitoring technology employed by the OxyLite is sensitive to temperature.

The error in the pO_2 reading due to a discrepancy between the temperature at the site of measurement and the temperature at which the sensor was calibrated (37°C) is dependent upon:

- The temperature range in question,
- The current pO_2 reading.

It can be approximated as follows.

For measurements in the range 30 - 45°C, the error in mmHg will be (1.2%) x (temperature discrepancy (i.e. temp error), in °C) x (displayed pO_2 reading in mmHg).

For example, if the site of measurement is at 42ºC, with the instrument set to 37 ºC and for a displayed reading of 50 mmHg of pO_2, the *actual* pO_2 reading will be approximately,

(50 mmHg) – (1.2% x 5 x 50 mmHg) = 50 mmHg - 3 mmHg = 47 mmHg.

i.e. in this instance the OxyLite will *over read* by 3 mmHg.

For measurements in the range 20 - 30°C, the error in mmHg will be (1.5%) x (temperature discrepancy (i.e. temp error) in °C) x (displayed pO_2 reading in mmHg).

For example, if the site of measurement is at 27ºC, with the instrument set to 37ºC and for a displayed reading of 140 mmHg of pO_2, the *actual* pO_2 reading will be approximately,

(140 mmHg) + (1.5% x 10 x 140) = 140 mmHg + 21 mmHg = 161 mmHg.

i.e. in this instance the OxyLite will *under read* by 21 mmHg.

To overcome this limitation, the OxyLite is capable of real-time temperature compensation across a limited temperature range.

Automatic temperature compensation requires a continuous temperature measurement from the tissue or sample under investigation and this is achieved by using combined OxyLite sensors that incorporate a fine thermocouple sensor ensuring that a temperature reading is obtained from the precise site of oxygen monitoring.

NOTE: While the thermocouple temperature sensors will accurately measure temperature in the range 0 – 50°C, temperature compensation has been validated within the range 10 – 45°C only. Oxygen measurements can be made outside of these limits (note: combined oxygen/temperature sensor required), however compensation accuracy has not been determined outside of these limits.

Manual temperature correction

Temperature compensation can also be achieved by manual temperature control using the SET button at the rear of the OxyLite monitor. This allows the use of less costly oxygen-only sensors in certain circumstances. Manual temperature control may suffice in situations where the temperature of the monitoring site or fluid is stable and known to within ±2 - 3ºC.

Any manual temperature setting is overridden as soon as a combined oxygen/temperature sensor is connected.

Any manual temperature setting is lost when the monitor is turned off. On start up, in the absence of a combined oxygen/temperature sensor, the instrument will default to 37ºC.

NOTE: Manual temperature compensation assumes that the temperature at the site of pO_2 monitoring is known to within a few degrees and unlikely to

fluctuate excessively. Inaccurate temperature compensation will result in erroneous pO_2 readings.

3.10 Digital (USB) Data Output

Our monitors now offer compatibility with the highly acclaimed LabChart® Pro data recording and analysis software by ADInstruments.

LabChart supports direct streaming of real-time recordings to a PC, via the dedicated USB output at the rear of the monitor.

Compatibility requires a dedicated and free software Add-on for LabChart (the 'Device Enabler'*), which supports automatic recognition of the Oxford Optronix monitor, the use of multiple Oxford Optronix monitors simultaneously and provides a choice of pre-loaded configuration settings specifically tailored to our monitors.

The Add-on also supports the simultaneous recording of data from an existing AD Instruments PowerLab® module.

A single LabChart Pro user license, inclusive of 5 years of free updates is available to order.

The Oxford Optronix Device Enabler can be downloaded via the 'Feature Manager' utility integral to LabChart.

Alternatively the Oxford Optronix Device Enabler is available for download from the 'Downloads' section of the ADInstruments website.

Dedicated instructions for setting up LabChart Pro for recording from OxyLite monitors can be found on our support site (www.oxford-optronix.com/support/supp_oxylite.htm).

*Notes: PC/Windows platforms supported only at this time; LabChart 8.0.4 or later required.

3.11 Analogue Data Outputs

Oxygen and temperature measurements can be recorded continuously on a PC or Macintosh computer via analogue outputs located at the rear of the OxyLite (see figure 2).

Analogue outputs consist of a pair of industry-standard, male Bayonet Neill–Concelman (BNC) connectors.

Output connector 'A' carries the Oxygen (pO_2) data output, while output connector 'B' carries the Temperature data output.

Data recording requires a third-party data acquisition module and accompanying software (optionally available from Oxford Optronix, see section 2.5), which will accept analogue input in the range -5V to +5V.

Generic female-female BNC cables (optionally available from Oxford Optronix; product 'OLO-BNC') provide compatibility with the vast majority of data acquisition systems.

The following table summarizes the unit conversion parameters required for data acquisition via the analogue outputs at the rear of the OxyLite monitor when using third-party data recorders (factory defaults shown):

Parameter	Oxygen (pO_2)	Temperature
Output voltage range	0 – 5V	0 – 5V
Zero output (0V)	0mmHg	0°C
Full scale output (5V)	200mmHg	50°C
Output resolution	40mmHg/V	10°C/V

Table 4: OxyLite analogue output unit conversion

The following table summarizes potentially diagnostic analogue output voltages during instrument boot-up and/or during error states:

Scenario	pO_2 output channel	Temp output channel
Initial boot	0V (typically)	0V (typically)
Instrument start-up	2.5V then 0V	2.5V then 0V
No Sensor	-2.5V	-2.5V
Negative measurement	Negative voltage	Negative voltage
Sensor expired	-1V	-1V
Sensor fault	-4V	-4V
Sensor error	-4V	-4V

Table 5: Diagnostic analogue output voltages

4. CARE OF OXYLITE

4.1 Use of OxyLite

OxyLite should only be operated on a secure, flat, horizontal surface and in ambient temperatures of 15°C to 30°C.

4.2 Cleaning and Storage of OxyLite

The monitor enclosure may be surface-cleaned by wiping lightly using a soft cloth dampened with a commercial, nonabrasive cleaner.

The monitor enclosure may be disinfected by wiping the surface with a soft cloth dampened with a solution of 70% alcohol in water.

WARNING

To avoid the risk of electric shock or shorts, do not spray, pour or spill any liquid in or on the OxyLite.

The OxyLite monitor should be stored between 10°C to 40°C. If returning from extremes of temperature, the unit should be allowed to acclimatise at room temperature for 30 minutes before use.

4.3 Handling and Storage of Sensors

The optical fibres employed within OxyLite sensors consist of glass, with a diameter of 230µm. The fibres are flexible and can be bent. However, it is recommended that they are not subjected to bends with a radius less than 30mm.

CAUTION

OxyLite sensors should be HANDLED WITH CARE.

Failure to do so may result in breakage of the internal optical fibre, loss of the oxygen sensing tip or separation of the cable from the sensor connector.

Sensor connectors must be kept clean and free from dust. Connectors should be inspected before use. Dust can be removed from the connectors using a good quality ‘air-duster’.

OxyLite sensors should be stored, with the sensor cable carefully coiled to avoid ‘kinks’, in the pouch in which they are provided and, ideally, in the dark (e.g. inside the closed cardboard container in which they are supplied), at or below room temperature.

DO NOT store OxyLite sensors in bright sunlight.

OxyLite sensors have a limited used or unused total shelf life and a recommended use-by date (printed on the sensor packaging). Both should be considered when establishing sensor inventories. Refer to section 3.7 for further information.

4.4 Cleaning, Disinfection and Sterilization of Sensors

Cleaning

OxyLite sensors are manufactured and packed in a controlled (clean) environment. The tips of OxyLite sensors can be cleaned after use by gentle wiping with water, or saline-soaked cotton wool / cotton gauze.

The oxygen sensing tips are fragile and can be damaged by attempts to clean them without due care and attention.

Disinfection

OxyLite sensors can be safely (and repeatedly) disinfected using 70% alcohol (industrial methylated spirit, IMS or isopropyl alcohol IPA) in water.

The sensor tip (beyond the Luer fitting) can be safely immersed in 70% alcohol while the white sleeving is best wiped with a non-linting cloth immersed in 70% alcohol.

Optionally, disinfection can be achieve by immersion of the complete sensor in 70% alcohol, although it is important to ensure that residual alcohol that may have become trapped within the sensor sleeving is allowed to fully drain away.

If the sensor connector has been immersed in 70% alcohol ensure that it is completely free of pockets of non-evaporated alcohol prior to use.

Sterilization

OxyLite sensors are NOT supplied pre-sterilized.

OxyLite sensors are NOT capable of withstanding sterilisation by dry or moist heat (autoclaving).

The materials and components used in OxyLite sensors may be compatible with exposure to ETO (ethylene oxide) gas.

The effect of exposure to heat, radiation, glutaraldehyde, ETO gas or plasma on the performance and measurement accuracy of OxyLite sensors has not been validated.

4.5 Disposal of Sensors

After use, failure and/or expiry, please dispose of sensors carefully and in accordance with local and national biohazard regulations and guidelines.

5. TROUBLESHOOTING AND MAINTENANCE

5.1 Troubleshooting

If you experience a problem using the OxyLite that you are unable to correct by reconnecting the sensor(s) and/or turning off and turning back on the monitor, please contact Oxford Optronix technical support (see p2 of this document).

Do not attempt to open the OxyLite. There are no user-serviceable parts inside. There is a risk of electrical shock or other injury or permanent damage to the monitor.

The following is a list of possible monitor errors / failure modes and suggestions for correcting them.

The monitor does not seem to power up

Check that the IEC mains lead is securely seated in the mains inlet at the rear of the monitor. Try and alternative IEC mains lead and connect it to an alternative wall socket.

If the problem persists please contact technical support.

The monitor is receiving power (the power-on LED on the front panel is lit) but there are no boot up 'beeps' or messages on the display

Turn the monitor off using the rocker switch at the rear and remove the IEC mains cable from the mains inlet. Replace the mains cable and turn the monitor back on. If the problem persists there is likely to be an electronic fault; in which case please contact technical support.

The monitor boots normally but does not respond to the connection of a sensor

Try power-cycling the monitor by turning it off and, after a delay of a couple of minutes, back on. If available try another sensor. If the problem persists there is likely to be a fault, in which case please contact technical support.

The monitor re-starts repeatedly mid-recording

Confirm that, a) you are operating within the recommended operating temperature and humidity limits for the monitor (see Specifications towards the back of this document), b) that the mains supply is stable and c) that there are no likely sources of electro-magnetic interference. Try turning off

the monitor for a period of 10 minutes and then turning it back on. If the problem persists there is likely to be a fault, in which case please contact technical support.

The analogue output signal is zero but the display shows readings above zero

There may be a cable problem. Check that the cable(s) attached to the analogue output connector(s) is/are securely seated and correctly configured at the data acquisition module end and at the back of the OxyLite. Check that the correct data channels are being viewed on the software package provided by the data acquisition module supplier. If the problem persists please contact technical support.

The '`Use Left | Cal.Expiry`' message does not clear automatically following connection of a sensor

This indicates that either the 'calibration period' or the 'accumulated longevity' parameter is in an expired state (see section 3.7). Press the SET button (section 3.6) at the rear of the monitor to clear.

The display reports a numerical sensor error

Refer to the table below for a summary of common sensor error codes. Please refer to the support website or contact technical support for error codes not listed.

Error displayed	Error description and suggestion
113	Low signal. Indicates that the sensor is not properly connected and/or that the oxygen-sensitive chemistry has become partially detached or photo-bleached. The sensor may be damaged and may need to be replaced. However it may still function in low oxygen environments (for example below 100 mmHg).
114	High signal. Indicates excessive ambient light conditions. Turn off any surgical light sources or cover the measurement area and wait a short while to see if the error disappears.
240	Error calculating pO2. May indicate that ambient light conditions are fluctuating more rapidly than the monitor can compensate for. Ensure ambient light conditions remain as constant as possible.

Table 6: Common sensor fault codes

The display reports a numerical fault

Try removing any sensors and power cycling the OxyLite. If the fault condition remains please contact technical support, reporting the numerical fault displayed.

Unexpectedly low oxygen readings

Sensors are subjected to strict quality control procedures prior to dispatch. Generally speaking, unexpectedly low oxygen readings have a physiological root cause (where used *in vivo*).

For example, the force exerted by the tip of an OxyLite sensor can easily exceed capillary closing pressure. Low pO_2 readings will result if this is the case. To overcome this situation, support the sensor cable and sensor tip area as neutrally as possible in such a way that the sensor is not exerting forward or lateral forces on the tissue. Withdrawing the sensor slightly, so that the tip is not at the end of the track created during placement, can reduce the pressure on the tissue.

Sensor placement is also commonly accompanied by a short-lived trauma response. Resultant vasoconstriction may generate low pO_2 readings for several minutes dependent on the tissue being examined. It is advisable to wait until the tissue has adjusted to the trauma and a steady pO_2 reading is obtained.

Another possible source for unexpectedly low oxygen measurements is inappropriate temperature compensation (refer to section 3.9 above). If the compensated temperature is greater than the actual temperature at the measurement site then the reported oxygen reading will be less than the true pO_2.

Unexpectedly high oxygen measurement

Sensors are subjected to strict quality control procedures prior to dispatch. Generally speaking, unexpectedly high oxygen readings have a physiological root cause (where used *in vivo*).

If a sensor is positioned very near the surface of a tissue, without sufficient tissue surrounding it to generate an effective seal, atmospheric oxygen may track along the sensor to the measurement area, resulting in high pO_2 readings. A better oxygen seal can be achieved by using a ‘purse stitch’ around the point of introduction or by positioning the sensor a little further into the tissue.

When a sensor is partially withdrawn from tissue or adjusted, the insertion point may open briefly allowing atmospheric oxygen to track to the measurement site. This may cause a transient in oxygen readings. Once the tissue re-closes around the sensor, the surplus oxygen will be consumed and normal readings will resume thereafter.

If the subject is being artificially respired using pure oxygen, the tissue pO_2 can exceed normal levels. Under these circumstances, it is possible that tissue pO_2 will exceed the range supported by the OxyLite (i.e. 200mmHg). With very high pO_2 the OxyLite may no longer report an oxygen value and report error state.

Another possible source for unexpectedly high oxygen measurements is inappropriate temperature compensation (refer to section 3.9 above). If the compensated temperature is less than the actual temperature at the measurement site then the reported oxygen reading will be greater than the true pO_2.

Erratic oxygen readings

Erratic readings, cessation of operation or other incorrect functioning may be evidence of electro-magnetic interference to the monitor (for example from a mobile phone). If this occurs, the place of use should be surveyed to determine if there may be a source for the disruption and actions should be taken to eliminate it, such as:

1) Turn equipment off in the vicinity of the monitor to isolate the equipment that may be generating the electro-magnetic interference.

2) Relocate the other device(s).

3) Increase the separation between the potentially interfering equipment and the OxyLite monitor.

5.2 Simple Sensor Functionality / Calibration Check

Sensors suspected of having failed or having sustained damage may be tested in a low-oxygen environment *in vitro*. The following section describes three recommended low or zero oxygen test conditions:

1. Pre-warmed (25 - 40°C) can of freshly opened soda (Cola, carbonated water, etc.).

2. Pre-warmed (25 - 40°C) water or saline in a glass conical flask continuously bubbled with nitrogen gas. Allow at least 5 minutes of continuous bubbling prior to introducing the sensor(s).

3. Freshly prepared 3% (w/v) solution of sodium sulphite (i.e. 3 grams of Na_2SO_3 in 100ml of water) in a glass vial (25 – 40°C). Stir well.

All of the above conditions should produce a stable measurement of oxygen in the 0 - 5mmHg range. Failure to produce a reading after 1 - 2 minutes and continued display of an error would indicate terminal damage to the sensor (most likely separation of the oxygen-sensitive chemistry).

5.3 Obtaining Technical Assistance

Contact information for obtaining technical assistance is provided on p2 of this manual and on the Oxford Optronix website.

When contacting Oxford Optronix technical support or your local distributor please provide the serial number of your monitor (found at the rear of the unit), the 6-digit alphanumeric sensor ID and details of the problem or error message(s) encountered.

5.4 Maintenance and Servicing

The OxyLite should only be repaired or serviced by Oxford Optronix Ltd. trained service staff.

Do not attempt to open the OxyLite. There are no user-serviceable parts inside. There is a risk of electrical shock or other injury or permanent damage to the monitor.

The monitor should be inspected regularly for signs of wear and tear.

The OxyLite monitor is supplied with a 2 year warranty. Please refer to the Terms and Conditions of the Warranty at the end of this user manual for further details.

Like all specialist laboratory equipment the OxyLite will benefit from regular servicing. The recommended service interval for OxyLite is every 2 years.

Servicing is strongly recommended to ensure continued optimal performance and operational reliability. Our maintenance service provides not only a complete technical/mechanical overhaul, update and recalibration but also ensures that your monitor receives the latest applicable software/firmware upgrades introduced as a result of our continuing R&D and product enhancement programmes.

Please contact technical support for detailed service schedules and pricing.

5.5 Returning the OxyLite Monitor

Contact Oxford Optronix or your local distributor for shipping instructions.

A **Returned Materials Authorisation** (RMA) number and completed **Decontamination Declaration form** MUST be obtained prior to shipping the equipment.

Pack the OxyLite in its original shipping carton where available. If the original carton is not available, pack the OxyLite in a suitably sized STURDY cardboard box ensuring that it is surrounded on ALL sides by at least 10 cm (4”) of tightly packed polystyrene chips, bubble wrap, foam or other suitable protective packing material.

For a small fee, Oxford Optronix can provide new original shipping cartons and foam inserts that will ensure safe transportation.

Failure to pack the OxyLite monitor appropriately for repair or service may result in potentially costly damage to the monitor during transit.

Sensors for return should be wrapped in protective material and packed in a suitably-sized strong box. Where accompanying a monitor for return these may be included within the larger carton for the monitor.

Use a recognized international courier company for the return of product to Oxford Optronix (e.g. UPS, FedEx, DHL etc).

Oxford Optronix will not accept responsibility for any loss or damage to goods shipped to us, howsoever caused.

6. TECHNICAL SPECIFICATIONS

Physical	
Dimensions	95mm (H) x 290mm (W) x 260mm (D)
Weight	2Kg / 4.5lbs
Operating temperature	10 - 30°C
Operating humidity	0 – 70% (non-condensing)
Power requirements	VAC 100-240V, 50-60Hz, 30W max.
Fuse rating	2 x T1.6A anti-surge
Display	High contrast 40 character alphanumeric OLED
Analogue voltage outputs	2 x male BNC connectors, 2 outputs
LED excitation wavelength	525nm
Luminescence wavelength	650nm

Performance	
Mode of operation	Luminescence decay lifetime (pO_2) / T-type thermocouple or manual user input (temperature)
Measurement units (displayed)	mmHg or kPa / ºC
Measurement range	0 – 200mmHg; 0 – 26.6kPa / 0 – 50ºC
Measurement resolution	0.1mmHg / 0.1ºC
Measurement accuracy	Oxygen: ±0.7mmHg (0 – 7mmHg) ±10% of reading (7 – 150mmHg) ±15% of reading (150 – 200mmHg) Temp: ±0.2ºC
Measurement T90 response time	< 20s (bare-fibre oxygen sensor) / < 2s (temperature)
Measurement sampling rate	1Hz
Measurement acquisition time	1s
Measurement time constant (filtering)	5s (Oxygen); 1s (Temperature)
Display update time	2s (5s rolling averaged)
Validated temp compensation range	10ºC – 45ºC
Sensor identification	Automatic; integrated connector EEPROM
Sensor calibration	Factory pre-calibration (unique per sensor); valid 6 months

Sensor shelf-life	2 years from factory calibration (used or unused)
Sensor longevity	48 hours accumulated usage
Analogue data output range	0 – 5V (0 – 200mmHg / 0 – 50ºC)
Analogue data output rate	1Hz

Table 7: OxyLite technical specifications

7 . WARRANTIES

7.1 Sensor Warranty

Oxford Optronix Ltd. warrants its sensors against defects in material or workmanship, when used in accordance with issued operating instructions.

Sensors are warranted for a single use only.

Oxford Optronix Ltd. is not liable under this warranty for defects arising from more than one insertion (or use) *in vivo*, and/or for continuous/accumulated operation in excess of 48 hours at the default sampling rate, and/or for operation in excess of 6 months from factory calibration.

Any re-use of sensors is carried out at the end-user's own risk and under the end-user's sole responsibility.

Oxford Optronix Ltd. specifically disclaims any other express or implied warranty, including warranties of merchantability and of fitness for use.

7.2 Monitor Warranty

Oxford Optronix Ltd. warrants its Products against defects in material or in workmanship, when used under appropriate conditions and in accordance with the appropriate Operating or User Instructions for a period of **24 months** from the date of purchase.

Oxford Optronix Ltd's sole obligation shall be to repair or to replace at Oxford Optronix' option, FOB its factory, without charge, any part(s) that prove defective within the warranty period. Software programs are supplied on the strict understanding that we do not warrant their functions to be free from defects, errors or bugs.

Any claim under the warranty must be made in writing. The Products to which the claim refers must be returned to us within 2 months from the date the claim was made, suitably packaged, using our Returned Materials Authorisation (RMA) procedure and our courier (e.g. FedEx) account reference. No returned Products will be accepted without prior written authorisation and an RMA number.

Oxford Optronix Ltd. is not liable under this warranty:
- for any defect arising from fair wear and tear, wilful damage, negligence, misuse, repair of the Products without our written approval; or
- any use of or dealing with the Products in conjunction with any other item where such item causes or gives rise to the alleged defect; or
- any use of the Products which is not in accordance with the Operating or

User Instructions or from any failure to service or maintain the Products in accordance with such instructions.

Oxford Optronix Ltd. specifically disclaims any other express or implied warranty, including warranties of merchantability and of fitness for use. To the full extent permitted by law, we shall not be liable in any way whatsoever whether in contract, in tort, in misrepresentation or under statute or common law or otherwise (whether caused by our negligence or otherwise) in respect of defects in the Products or failure to correspond to specification or for any injury, damage or loss resulting from such defects or failure. In no event shall any breach of contract on our part or tort (including negligence) or failure of any kind on our part give rise to any liability for loss of revenue or loss of profits or any other consequential or indirect loss or damage arising from any cause whatsoever.