User Manual

OxyFlo™

Continuous laser Doppler blood flow monitoring

Product Documentation and User Manual

Revision 1.1

Designed and Manufactured by:

Oxford Optronix Ltd.
19-21 East Central
127 Olympic Avenue
Milton Park
Oxford OX14 4SA
United Kingdom

t: +44 (0)1235 821 803
f: +44 (0)1235 821 678

Primary website: www.oxford-optronix.com
Sales email: sales@oxford-optronix.com

Support website: www.oxford-optronix.com/support/supp_oxyflo.htm
Support email: support@oxford-optronix.com

Table of Contents

Figures

Tables

1. SAFETY INFORMATION

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

1.1 Intended Use

The OxyFlo is a laser Doppler blood flowmetry (LDF) monitor intended for monitoring microvascular blood flow in tissue.

Most applications are concerned with monitoring the competence of regional (microvascular) blood supply in specialties such as peripheral vascular disorders, cerebral perfusion monitoring in models of stroke and brain injury, tumour perfusion monitoring / angiogenesis, blood flow in free flaps and pedicle flaps, wound healing, surgery, transplantation and more.

A range of fibre-optic based probes is available in support of these application areas, including small and lightweight probes for (non-invasive) skin and tissue surface measurements and needle type probes for direct (invasive) measurements within tissue, such as muscle and vitals organs.

In common with all LDF devices, quantitative measurements of tissue blood flow in absolute units (e.g. ml/min/g of tissue) are **not** possible with the OxyFlo.

The OxyFlo has been specifically developed for use with the OxyLite, a fibre optic tissue pO_2 and temperature monitor. 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 flow monitoring.

1.2 Contra-Indications

The OxyFlo is purely for laboratory, industrial and research use and is NOT a medical device. The OxyFlo does NOT possess regulatory approvals 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 the 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 Laser Safety

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Never apply an OxyFlobe directly to the eye. The laser exposure may cause permanent damage to the retina.

OxyFlo is classified as a Class 1 Laser Product in accordance with the European Standard EN 60825-1:1994 and 21 CFR 1040.10 and 1040.11. In accordance with the standard, the back panel of the monitor carries the declaration:

Class 1 Laser Product

OxyFlo incorporates semiconductor laser diode devices operating in continuous mode and emitting invisible laser radiation at a nominal operating wavelength of 830nm. The maximum output power at the probe tip is less than 0.5mW. Laser light emitted from the optical fibre is highly divergent.

Although the characteristics of the laser radiation place the OxyFlo device within the Class 1 classification, users should avoid directing the laser radiation onto the eye.

Applying the probe to any tissue other than the eye is harmless, even over prolonged time periods.

1.6 OxyFlo 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: OxyFlo symbols

1.7 Definitions

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

1.8 Summary of Warnings for the OxyFlo Monitor

 WARNING	Do not attempt to open the OxyFlo. 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 OxyFlo 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 OxyFlo.
 WARNING	Never apply an OxyFlo probe directly to the eye. The laser exposure may cause permanent damage to the retina.

1.9 Summary of Cautions for the OxyFlo Monitor

 CAUTION	DO NOT attempt to operate the OxyFlo 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. Extended probe lengths are available that allow the OxyFlo monitor to be operated at a safe distance from such equipment.
 CAUTION	DO NOT attempt to autoclave, pressure sterilise, or expose to radiation, any part of the monitor.
 CAUTION	Attempting to disconnect the probe by pulling the cable sleeving instead of the probe connector may cause irreparable damage to the probe.
 CAUTION	Use only probes, cables and accessories supplied by Oxford Optronix Ltd., otherwise serious damage may result.
 CAUTION	Failure to pack the OxyFlo monitor appropriately for repair or service may result in potentially costly damage to the monitor during transit.

1.10 Summary of Cautions for OxyFlo Probes

 **CAUTION**	OxyFlo probes must be HANDLED WITH CARE. Failure to do so may result in breakage of the internal optical fibres, scratching the polished probe ends or separation of the cable from the probe ends or connectors.
 **CAUTION**	OxyFlo probes are NOT approved for use on patients.
 **CAUTION**	Attempting to disconnect the probe by pulling the cable sleeving instead of the probe connector may cause irreparable damage to the probe.
 **CAUTION**	DO NOT drop, apply tension or ‘kink’ any part of an OxyFlo probe. Permanent damage may result.
 **CAUTION**	OxyFlo probes should be stored, with the probe cable carefully coiled to avoid ‘kinks’, in the dedicated protective case in which they are supplied.
 **CAUTION**	Do not use a probe if it appears worn or damaged.
 **CAUTION**	Avoid immersing the probe *connector* in any cleaning solution.
 **CAUTION**	If the probe connector has been immersed in 70% alcohol ensure that it is completely free of pockets of non-evaporated alcohol prior to use.
 **CAUTION**	The effectiveness of ETO gas, radiation or plasma methods for probe sterilization has not been validated.
 **CAUTION**	It is the responsibility of the user to validate the sterility of OxyFlo probes after sterilisation.

1.11 Summary of Cautions for Probe Calibration

 CAUTION	It is essential that the calibration procedure is performed on a stable and vibration-free surface. Any movement or vibration during the calibration procedure - however slight - is likely to result in a failed calibration.
 CAUTION	The motility standard has a limited life. The expiry date is indicated on the label. The solution must not be used beyond this date, as it may produce misleading values due to the gradual aggregation of the latex spheres.
 CAUTION	Do not use the motility standard in ambient temperatures below 15ºC or above 25ºC.
 CAUTION	Store the motility standard within the temperature range 3 – 25ºC. DO NOT FREEZE the solution.
 CAUTION	Do not dilute the motility standard.
 CAUTION	It is important that all probes to be used with any one OxyFlo monitor have *different probe identification numbers* in order to prevent possible probe calibration errors. Please contact technical support for advice.

2. INTRODUCTION

2.1 General description

The OxyFlo is a microvascular blood flow monitor that is capable of monitoring red blood cell (erythrocyte) perfusion in the microcirculation of a tissue.

The monitor uses a technique referred to as Laser Doppler Flowmetry (LDF), an established and reliable method for the measurement of blood perfusion in microvascular research.

OxyFlo probes plug into the OxyFlo monitor, which contains the laser source and sensitive photo-detection and signal processing circuitry.

Probes are standardised using a reference motility standard consisting of latex microspheres undergoing Brownian motion.

Microvascular blood flow is indicated on the integrated OLED display in relative units called Blood Perfusion Units (BPU).

2.2 List of Key Features

- Continuous tissue blood flow assessment
  Uncompromised reliability in continuous tissue blood flow assessment; ideally suited to measurements of changing tissue blood flow in acute experimental models.
- Versatility
  A range of probe types and probe formats provide support for a host of specialist disciplines and applications requiring either invasive or non-invasive tissue blood flow assessment.
- Plug and play
  Probes require no calibration procedures or configuration following one-time probe calibration. Probes supplied at the time of monitor shipment are supplied factor pre-calibrated.
- Multi-parameter monitoring
  Our OxyFlo blood flow monitors are designed specifically to be used in tandem with our OxyLite range of oxygen monitors, providing support for simultaneous measurements of tissue oxygenation, blood flow and temperature from each combined sensor.
- 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 data 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
  Our inclusive manufacturer's warranty covers defects in material, function or in workmanship for a period of 2 years following delivery.

2.3 Laser Doppler flowmetry and the OxyFlo

Laser Doppler Flowmetry ('LDF') is an established and reliable method for the measurement of blood perfusion in microvascular research that in no way harms or disturbs the normal physiological state of the microcirculation.

The OxyFlo blood flow monitor implements this method by illuminating tissue with low power laser light using a probe containing optical fibre light guides. Laser light from one fibre is scattered within the tissue and some is scattered back to the probe. A second optical fibre collects the backscattered light from the tissue and returns it to the monitor. Most of the light is scattered by tissue that is not moving but a small percentage of the returned light is scattered by moving red blood cells. The light returned to the monitor undergoes signal processing to extract the signal related to the moving red blood cells.

Laser Doppler signals from the tissue are recorded in BPU (Blood Perfusion Units) which is a relative units scale defined relative to a carefully controlled motility standard comprising a suspension of latex spheres undergoing Brownian motion.

Perfusion is also referred to as tissue blood flow, microvascular blood flow or red blood cell flux.

In common with all LDF devices the OxyFlo generates arbitrary, non-absolute units of tissue blood flow since the tissue sampling volume cannot be reliably established. Thus, LDF is best suited to observations of continuous, acute changes in blood flow relative to a baseline (control) obtained within the same experiment.

In other words, measurements obtained by LDF are intrinsically of a relative nature; although such measurements are proportional to perfusion, the factor of proportionality will be different for different tissues.

2.4 Measurement parameters generated by the OxyFlo

The blood flow (BPU) parameter

The primary function of the OxyFlo is to produce a tissue blood flow output signal that is proportional to the red blood cell perfusion (or flux) in the area of tissue being investigated. This represents the transport of blood cells through the microvasculature and is defined as,

Tissue blood flow	=	Number of blood cells moving in the tissue sampling volume	x	Mean velocity of these cells

Tissue blood flow therefore, is the product of mean blood cell velocity and mean blood cell number (concentration) present in the measuring volume of tissue under illumination from the probe.

For the OxyFlo, tissue blood flow is indicated in relative units called Blood Perfusion Units (BPU). All OxyFlo monitors have been calibrated with a constant, known motility standard so that, for a given blood flow situation, all OxyFlo probes will read the same value of blood flow expressed in BPU.

The standard BPU output has been optimally filtered with a time constant of 200ms to give a clean and smooth looking signal whilst able to respond to dynamic changes and pulsatile blood flow changes.

The blood flow parameter is output on the primary data channel.

The ‘Backscatter’ parameter

The OxyFlo also generates a signal which is proportional to the total light remitted or backscattered from the tissue. This is called the Backscatter Signal (BS).

Backscatter is expressed as a percentage (%) fraction of the laser light remitted from the tissue relative to the total amount of laser light incident on the tissue.

For example, in highly perfused tissues the BS will be low due to increased photon absorption. Situations where the BS signal is close to zero may indicate that the probe has come into contact with whole blood, this could cause the BPU reading to saturate since the system is no longer monitoring microvascular blood flow.

The backscatter parameter is output on the secondary data channel.

2.5 The OxyFlo Monitor

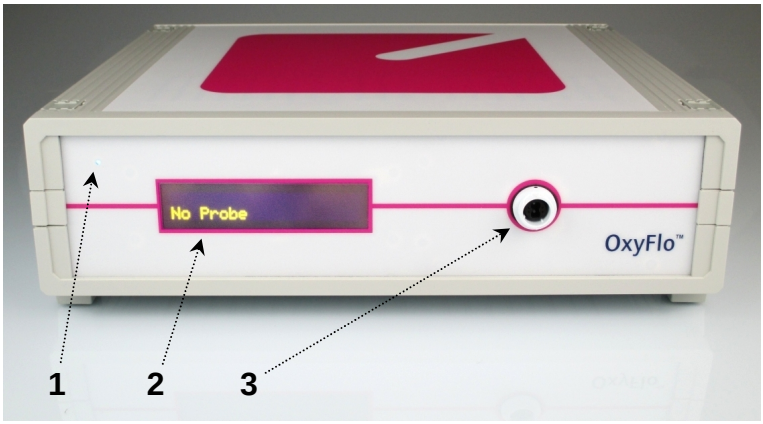


Figure 1: Front view of the OxyFlo

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

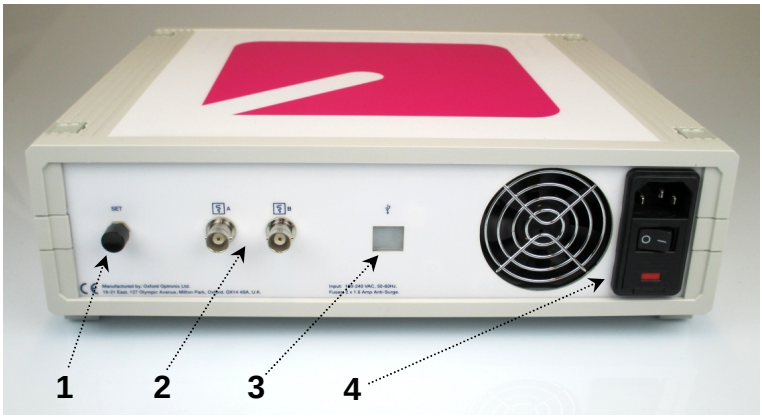


Figure 2: Rear view of the OxyFlo

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

2.6 OxyFlo Probes

Introduction

A comprehensive range of Laser Doppler probes is available for use with the OxyFlo monitor, a description of which can be found on our website (www.oxford-optronix.com).

All probes are comprised of a pair of 125 µm optical fibres, which are used to direct low power laser light to and from the tissue. The fibres terminate at one end of the probe in the probe head (of variable design, depending on probe type) and at the other end in a connector plug that attaches to the OxyFlo. The connector plug is colour-coded with a **red** band.

OxyFlo probes are either referred to as 'dedicated blood flow probes', for the exclusive measurement of tissue blood flow, or as 'combined sensors' for the simultaneous measurement of tissue blood flow and tissue pO_2/temperature, where the OxyFlo is used in conjunction with its optional counterpart, the OxyLite.

The number of plugs on a sensor is dependent on the number of parameters being measured. Dedicated blood flow probes feature a single plug, while combined sensors featuring support for tissue pO_2/temperature measurements (and requiring the counterpart OxyLite monitor), feature *two* connector plugs.

In the case of combined sensors, the connector plug carrying the oxygen/temperature signal is colour coded with a **blue** band.

Probe Presentation

OxyFlo probes consist of a pair of optical fibres used to direct weak laser light to and from the probe head.

The fibres terminate at one end in the probe head (MSP300NX surface probe type depicted here) and, at the other end, in a connector plug that attaches to the OxyFlo (colour-coded with a red band).

A durable white silicone sleeving serves to protect the optical fibres along the 3 m length of the probe.

('MSP300NX' type depicted)

Figure 3: An OxyFlo probe ('MSP300NX' type depicted)

 CAUTION	OxyFlo probes must be HANDLED WITH CARE. Failure to do so may result in breakage of the internal optical fibres, scratching the polished probe ends or separation of the cable from the probe ends or connectors.
 CAUTION	The optical fibres used in OxyFlo probes consist of glass with a diameter of 125 µm. The fibres are flexible and can be bent, however it is recommended that they are not subjected to bends with a radius of less than 30mm.
 CAUTION	DO NOT drop, apply tension or 'kink' any part of an OxyFlo probe. Permanent damage may result.
 CAUTION	Attempting to disconnect the probe by pulling the cable sleeving instead of the probe connector may cause irreparable damage to the probe.
 CAUTION	OxyFlo probes are NOT approved for use on patients.
 CAUTION	OxyFlo probes should be stored, with the probe cable carefully coiled to avoid 'kinks', in the dedicated protective case in which they are supplied.
 CAUTION	Avoid using OxyFlo probes under strong (e.g. surgical) lights.

2.7 Accessories

The following accessories are available from Oxford Optronix Ltd. for use with the OxyFlo;

Product Code	Product Description
CAL KIT	Calibration kit for LDF probes and MSFD NX adapter
MSP140AR	Double-sided adhesive rings for surface LDF probes. Pack of 200
MH-10	Miniature holders (10mm diam) for MNP100NX-3/10 probe. Pack of 5

MH-05	Miniature holders (5mm diam) for MNP100NX-3/10 probe. Pack of 5
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 ADInstruments

Table 2: Available accessories for OxyFlo

Use only probes, cables and accessories supplied by Oxford Optronix Ltd., otherwise serious damage may result.

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 OxyFlo 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 OxyFlo safely at servicing intervals.

3.2 List of Standard Components

- OxyFlo 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 close to the point of measurement. Note that the standard probe cable length is 3 metres (approx. 10 feet).
2. Ensure that the power On/Off switch at the rear of the OxyFlo is in the OFF (0) position.
3. Plug the IEC power cable into the IEC mains inlet at the rear of the OxyFlo 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 OxyFlo. 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. 15 seconds).

   During this time there will be two audible ‘beeps’ approx. 2 seconds apart and the display will show a number of messages (see section 3.5) including confirmation of internal software version.
5. Once the display shows ‘No Probe’ the monitor is ready for probe connection and use (see section 3.4).

3.4 Connecting / Disconnecting Probes

The OxyFlo automatically recognises previously calibrated probes and applies the necessary probe calibration coefficients on connection. This essentially alleviates the requirement for repeated re-calibration.

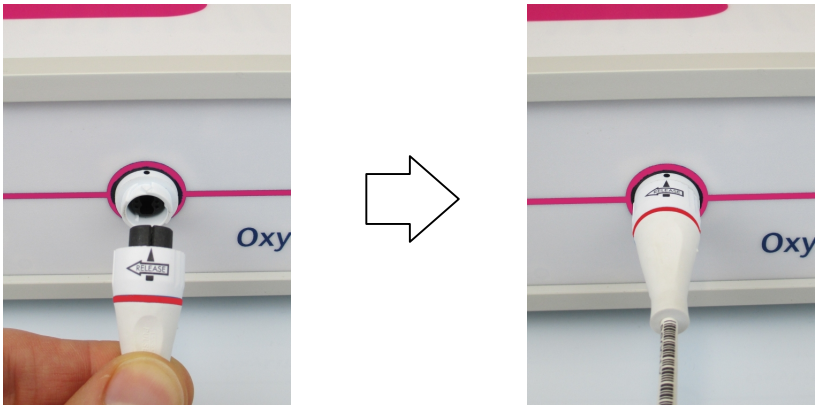


Figure 4: Connecting and disconnecting a probe

Align the probe 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, the probe ID will be read and calibration coefficients loaded automatically by the monitor (provided the probe has been either factory-calibrated or calibrated by the user – see instructions below).

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

CAUTION

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

3.5 Display Messages

The OxyFlo front panel displays blood flow and backscatter measurements when a probe 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 OxyFlo boot sequence. The message is followed by two audible 'beeps', approx. 2s apart. Analogue output during this time is 2.5V (50% scale).
OxyFlo Version PCL 1.15	Second message displayed during the boot sequence. Confirms instrument model and internal software version. Analogue output during this time is 2.5V (50% scale).
No Probe	There is no probe connected to the OxyFlo but the monitor has completed its boot sequence and is ready for use. Analogue output during this time is -2.5V (-50% scale).
Probe ID=nn	When a probe is connected the probe ID is briefly displayed.
1234 BPU 85%BS Probe ID: nn	Normal display with a calibrated probe connected, showing blood flow and backscatter measurements, as well as the probe ID.
Calibrate Probe Probe=nn	Displayed when a probe is connected that has not been calibrated on the monitor. The probe (ID as displayed) requires calibration prior to use.

Calibration Dip Probe	Displayed when the CAL button is pressed once. An audible beep will sound every two seconds. Refer to section 3.6.
Calibration Probe=nn	Displayed when the CAL button is pressed a second time. A long beep will sound and probe calibration will proceed. Refer to section 3.6.
Calibration CAUTION	Displayed while the calibration is in progress. Refer to section 3.6.
Calibration Cal OK	Confirms that calibration was successful.
Calibration Error = n	Error message displayed when a calibration was not successful. The message is accompanied by a long audible 'beep' followed by a number of short 'beeps' corresponding to the error number. Refer to section 3.6.
Calibration Aborted	Indicates that the calibration process has been cancelled as the CAL button was not pressed a second time.
Temp. out of Range	Indicates that the internal temperature of the monitor is outside the limits for stable operation. Refer to section 5.1.

Table 3: OxyFlo display messages

3.6 Probe Calibration

The OxyFlo monitor is designed to automatically recognise and apply the correct calibration coefficient when a probe is connected.

Probes purchased with a monitor will be calibrated at the factory. Since the calibration data is stored within the monitor, if a probe has previously been calibrated, then calibration coefficients will be loaded automatically and the probe will be ready to use almost immediately.

Where additional probes are purchased from Oxford Optronix Ltd. subsequent to monitor delivery, a one-time user calibration is required.

IMPORTANT:
For users wishing to use combined blood flow and oxygen/temperature sensors (requiring the counter part OxyLite oxygen/temperature monitor), there is NO REQUIREMENT to carry out individual flow calibration. These sensors will be recognized automatically by the OxyFlo with a 'generic' probe ID of 25.

When the calibration procedure ends, the calibration data for that particular probe is automatically stored within the monitor. The calibration data is then automatically retrieved every time that particular probe is connected to the monitor.

Every probe features a probe ID number (between 1 and 26) that the monitor 'reads' each time the probe is connected. The probe ID is confirmed on the display when the probe is connected.

Probe identification numbers are assigned such that no two probes (issued to the same user) feature the same ID.

The exception to this rule are combined blood flow and oxygen/temperature sensors (requiring the counterpart OxyLite monitor), which feature a fixed ID number (25).

There is no recommended re-calibration interval for probes; generally speaking probe calibration coefficients should remain valid for a number of months or even years.

Calibration Procedure

To perform a new probe calibration, you will require a Calibration Kit (product code CAL KIT) which consists of a motility standard and a positioning clamp. The motility standard is a solution of latex spheres at a precisely defined concentration. The positioning clamp is used to maintain the probe in the solution.

IMPORTANT: In order for the calibration to succeed, it is crucial that the probe and calibration solution are not subjected to vibration or movement of any kind during the calibration procedure.

IMPORTANT: Do not use the motility standard in ambient temperatures below 15ºC or above 25ºC.

Proceed as follows to calibrate a probe:

1. Gently swirl the bottle to disperse the contents before use.
2. Open the bottle and allow the contents to settle for one minute before proceeding.
3. Carefully position the probe into the solution. This is best achieved by grasping the probe cable within the jaws of the clamp and carefully lowering the active area of the probe into the centre of the solution as shown:

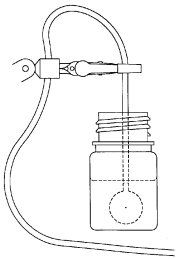


Figure 5: Preparing a probe for calibration

Keep the active probe surface or probe tip away from the edges or the bottom of the bottle. The probe should be supported in such a way that it does not swing or move whilst in the solution.

4. Connect the probe that you wish to calibrate to the OxyFlo.

   NOTE: If the probe has not previously been calibrated the display will show a '`Calibrate Probe`' message.

5. Locate the 'SET' button at the rear of the monitor (see figure 2) and press it once to initiate the calibration routine. The display will show '`Calibration – Dip Probe`' accompanied by an audible 'beep' every 2 seconds.
6. Press the SET button a second time within 10 seconds to trigger the calibration. A 5s continuous audible 'beep' is emitted while the message '`Calibration – Probe=nn`' is displayed. This is followed by the message '`Calibration – CAUTION`' while the calibration is in progress.

   IMPORTANT: This 20 - 30 second period is where any vibration or movement will cause the calibration procedure to fail.

   If the calibration is successful the message '`Calibration – Cal OK`' is displayed accompanied by an audible double 'beep'.

The display will then begin showing blood flow and backscatter measurements. Blood flow readings from the calibration solution should be in the region of 1,000 BPU (+/- 50 BPU).

Re-calibration of Probes

Probes can be re-calibrated at any time following the exact procedure described above.

Failed Calibration

A failed calibration will be indicated by a long continuous audible 'beep' followed by a series of short 'beeps' corresponding to the error number identified (displayed with the message '`Calibration – Error = n`').

There are 6 error codes, as follows:

Error	Probable cause	Remedial action
1, 3, 4	Incorrect probe position or malfunctioning probe	Reposition probe in motility standard solution and repeat calibration. Repeat calibration as necessary.
2	Signal level low	May indicate probe or internal fibre damage. Check for fibre integrity (see section 5.2).
5, 6	Vibration or probe/cable movement	Ensure motility standard solution is on a vibration-free surface and that probe and cable movement is eliminated. Repeat calibration as necessary.

Table 4: Calibration error codes

 **CAUTION**	It is essential that the calibration procedure is performed on a stable and vibration-free surface. Any movement or vibration during the calibration procedure - however slight - is likely to result in a failed calibration.
 **CAUTION**	The motility standard has a limited life. The expiry date is indicated on the label. The solution must not be used beyond this date, as it may produce misleading values due to the gradual aggregation of the latex spheres.
 **CAUTION**	Do not use the motility standard in ambient temperatures below 15ºC or above 25ºC.

CAUTION	Store the motility standard within the temperature range 3 – 25ºC. DO NOT FREEZE the solution.
CAUTION	Do not dilute the motility standard.
CAUTION	It is important that all probes to be used with any one OxyFlo monitor have *different probe identification numbers* in order to prevent possible probe calibration errors. Please contact technical support for advice.

3.7 Placement of Probes

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

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

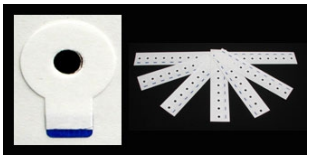
IMPORTANT: In all cases direct 'occlusive' pressure on the tissue under investigation and tissue or probe movement must be avoided as far as possible.

In summary:

Recommendations for probe placement depend primarily on the probe type being used.

Surface probes

Surface type probes (e.g. MSP310NX or MSP300NX) may be attached to skin or dry tissue surfaces using our double-sided adhesive rings (product code MSP140AR),



Alternatively, our suturable surface probe (MSP300NX) is designed to be sutured directly onto a tissue surface.

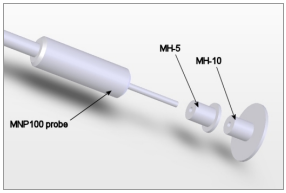
Needle probes

Needle style probes have a blunt end and, where used for invasive measurements, should generally be inserted into tissue with the use of a suitable introducer (e.g. Angiocath™) or following the creation of an appropriate incision.

For non-invasive use, needle probes can be placed above the tissue such that the tip is in gentle contact with, or very close proximity to, the tissue. Ensuring that the probe is maintained in a perpendicular position will help maximize signal quality and minimize the effects of ambient light.

Optionally needle probes may be mounted in a micromanipulator assembly or stand.

Our needle type probe for MCAO applications (MNP100NX-3/10) can be secured to bone (skull) via dedicated miniature holders (product code MH-05/MH-10),



3.8 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 OxyFlo monitors can be found on our support site (www.oxford-optronix.com/support/supp_oxyflo.htm).

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

3.9 Analogue Data Outputs

Blood flow measurements can be recorded continuously to a PC or Macintosh computer via analogue outputs located at the rear of the OxyFlo (see figure 2).

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

Output connector 'A' carries the 'Backscatter' data output, while output connector 'B' carries the 'Flow' data output.

Data recording requires a third-party data acquisition module and accompanying software (optionally available from Oxford Optronix, see section 2.7), 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 OxyFlo monitor when using third-party data recorders (factory defaults shown):

Parameter	Blood Flow	Backscatter
Output voltage range	0 – 5V	0 – 5V
Zero output (0V)	0 BPU	0%
Full scale output (5V)	5000 BPU	100%
Output resolution	1000 BPU/V	20%/V

Table 5: OxyFlo analogue output unit conversion

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

Scenario	Blood Flow output	Backscatter output
Initial boot	0V (typically)	0V (typically)
Instrument start-up	2.5V	2.5V
No Probe	-2.5V	0V

Table 6: Diagnostic analogue output voltages

4. CARE OF OXYFLO

4.1 Use of OxyFlo

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

4.2 Cleaning and Storage of OxyFlo

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 OxyFlo.

The OxyFlo should be stored between 10°C to 40°C. When 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 Probes

The optical fibres used within the OxyFlo probes consist of glass, with a diameter of 125µm. 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	OxyFlo probes must be HANDLED WITH CARE. Failure to do so may result in breakage of the internal optical fibres, scratching the polished probe ends or separation of the cable from the probe ends or connectors.
 CAUTION	OxyFlo probes should be stored, with the probe cable carefully coiled to avoid ‘kinks’, in the dedicated protective case in which they are supplied.

Probe 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’.

OxyFlo probes should be stored, with the probe cable carefully coiled to avoid ‘kinks’, in the dedicated protective case in which they are supplied.

The integrity of OxyFlo probes may be checked by holding the probe end to a source of bright light and inspecting the connector end for two spots equally intense light from the pins within the connector (refer to section 5.2).

4.4 Cleaning, Disinfection and Sterilization of Probes

Cleaning

OxyFlo probes are cleaned prior to packaging and dispatch. It is recommended that the probe end on all new probes be wiped with a soft cloth, preferably one that does not shed fibres, impregnated with 70% alcohol in water.

It is recommended that after use probes are cleaned immediately as it is easier to remove soiling and particulate matter before it dries onto surfaces, as follows:

- Visually inspect the probe end, cable and connector. If there is no visible soiling, wipe the probe end and cable with a soft cloth impregnated with 70% alcohol in water. Allow the alcohol to dry completely before reusing the probe.
- If there is visible soiling, clean the probe with warm water containing a mild detergent.
- Careful rubbing with a soft cloth or brush should be employed to ensure that all soiling and particulate matter is removed. These actions should be carried out beneath the surface of the cleaning solution.
- Rinse the probe end and cable in clean water.
- Wipe the probe end and cable (without stretching it) with an absorbent cloth and leave the probe to dry.

Avoid immersing the probe *connector* in any cleaning solution.

Disinfection

OxyFlo probes can be disinfected by immersion of the probe end and cable in either 2% gluteraldehyde or in 70% alcohol (industrial methylated spirit, IMS or isopropyl alcohol IPA) in water.

The disinfectant manufacturer's recommended immersion times should be used.

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

Sterilization

OxyFlo probes are not supplied sterile.

OxyFlo probes are NOT capable of withstanding sterilisation by dry or moist heat (autoclaving).

The materials and components used in OxyFlo probes may be compatible with ETO (ethylene oxide) gas, radiation and plasma sterilization methods.

 CAUTION	The effectiveness of ETO gas, radiation or plasma methods for probe sterilization has not been validated.
 CAUTION	It is the responsibility of the user to validate the sterility of OxyFlo probes after sterilisation.
 CAUTION	DO NOT attempt to autoclave, pressure sterilise, or expose to radiation, any part of the monitor.

4.5 Disposal of Probes

After use, failure and/or expiry, please dispose of probes 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 OxyFlo that you are unable to correct by reconnecting a probe 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 OxyFlo. 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 display indicates '`No Probe`' even though a probe is connected

This is likely to be a problem with the probe. Try a spare probe if available and/or carry out the simple probe integrity check (section 5.2). If the problem persists please contact technical support.

The display indicates '`Calibrate Probe`'

Probe calibration is required. Follow the instructions provided in section 3.6.

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 probe

Try power-cycling the monitor by turning it off and, after a delay of a couple of minutes, back on. If available try another probe. 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.

There is a continuous sound upon power-on

The monitor has failed the power-on self-test. If the problem repeats itself after multiple power-on attempts contact technical support.

There is an audible 'beep' every 5 seconds and a '`Temp out of` Range' message on the display

If the internal temperature of the OxyFlo monitor rises above the maximum permitted internal operating temperature threshold then the message 'Temp out of Range' will appear on the display. If this occurs check that the fan at the rear of the OxyFlo is not obstructed and/or move the instrument to a cooler location. Analogue outputs will continue but the readings will not appear on the display. Data generated during this condition may no longer be within the calibrated tolerance of the system and should be interpreted with caution.

If the ambient temperature is 'normal' (typically 18-25ºC) and this message occurs repeatedly soon after power-on, then a fault may have occurred and you should contact technical support for further advice.

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 OxyFlo. 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.

Calibration of a probe generates an error message and audible 'beeps'

Please refer to section 3.6 above (Probe Calibration).

Erratic Flow (BPU) values / signal artefacts

Certain environmental conditions and probe application and positioning errors can affect the reliability of laser Doppler blood flow readings.

Irrespective of the probe used, it is important to reduce the possibility of signal artefact, noise and signal dropout in the blood flow reading.

The presence of motion artefact noise in the blood perfusion signal is often due to relative movements of the tissue (e.g. induced by breathing) with respect to the probe and/or probe cable movements. These artefacts can be minimised by allowing the probe to come into contact with the tissue such that the probe and tissue 'move in unison' and by ensuring the cables do not move. It may be helpful to secure the probe cable to the table at intervals with adhesive tape.

It is also essential to ensure that undue probe pressure is not applied to the tissue; otherwise local occlusion of the microvasculature may result in a corresponding reduced blood flow reading.

Excessive ambient lighting at the probe measurement site can also disturb the blood flow reading. Avoid direct illumination of the measurement site from external lighting sources and direct sunlight. If erroneous readings due to excessive ambient lighting levels are suspected, cover the measurement area with a light piece of opaque material.

In summary, avoid the following situations:

- Strong ambient lighting sources such as surgical lights
- Fluctuating ambient lighting
- Probe movement relative to the tissue
- Movement of the probe cable
- Excessive physical pressure of the probe against the tissue under investigation

Baseline blood flow values vary widely between measurements

The laser Doppler flowmetry technique provides only arbitrary, non-absolute units of tissue blood flow since the sampling volume/depth cannot be reliably determined and thus a probe may generate widely varying baseline values from the same/similar tissue site/region at every placement.

The OxyFlo may not therefore be suited to the non-continuous or repeated assessment of changes in tissue blood flow over chronic time periods. The strengths of the laser-Doppler technique lie in observing continuous, *acute* changes in blood flow relative to a baseline (control).

What is the Meaning of Zero and Negative BPU?

The calibrated zero reading has been obtained by calibrating the system against a special static scattering material where no movements occur. In such cases the back-scattered light processed by the OxyFlo contains no Doppler shifted frequency components and a true zero is obtained. In a true physical sense, 'noise' around zero can be both positive and negative, thus it is possible that a small negative reading (of up to –10 BPU) can be observed in conditions of zero perfusion.

A zero reading indicates zero motion both in the measuring volume under examination and artefactual motion arising from relative movements between the probe and the measuring volume. During *in vivo* measurements, rarely is an absolute zero obtained. Even during total occlusion of tissue blood flow, there is often some small, residual motion of blood cells trapped in the vessels, as well as some small muscle and tissue movement in the measuring volume. Even after surgical removal of tissue, localised red blood cell movement and Brownian motion may still occur.

5.2 Simple Probe Integrity Check

The integrity of the optical fibres within OxyFlo probes can be checked by holding the probe end to a source of bright diffuse light (e.g. a ceiling light) whilst visually inspecting the connector end. Two bright spots of light of equal intensity should be visible from the two pins within the connector. The light spots may be more obvious if the probe end is slowly waved across the light source repeatedly.

If light is visible from just a single pin or if light from one of the pins is obviously dimmer than the other then this indicates either a fibre-break or fibre damage. Generally (but not in all cases) such damage can be repaired; please contact technical support accordingly.

5.3 Obtaining Technical Assistance

Contact information for obtaining technical assistance is provided at the beginning of this manual and on the Oxford Optronix web site.

When contacting technical support or your local distributor please provide the serial number of your monitor (found at the rear of the unit), details of probe type(s) used, the nature of the application, and details of the problem or error message(s) encountered.

5.4 Maintenance and Servicing

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

Do not attempt to open the OxyFlo. 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 OxyFlo monitor is supplied with a 2 year warranty. Please refer to the Terms and Conditions of the Warranty at the end of this document for further details.

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

Whilst optional, servicing is strongly recommended to ensure continued optimal performance and operational reliability. Our maintenance servicing 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 OxyFlo 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 OxyFlo in its original shipping carton where available. If the original carton is not available, pack the OxyFlo 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 OxyFlo monitor appropriately for repair or service may result in potentially costly damage to the monitor during transit.

Probes for return should be shipped in their original, dedicated sturdy plastic cases, inside either a large padded envelope or packed in a suitably-sized box. Where accompanying a monitor for return, probes may be included within the larger carton of the monitor, provided there is suitable protective material between them.

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
Laser type	Temperature-stabilized semi-conductor laser diode
Laser wavelength	830 ± 10nm
Laser classification	Class 1 (EN 60825-1 and 21 CFR 1040.10)
Laser power	<0.5mW from probe tip/underside

Performance	
Mode of operation	Laser Doppler Flowmetry
Measurement units (displayed)	0 – 9999 BPU (blood perfusion units)
Stability of reading	± 5%
Measurement sampling rate	200Hz
Measurement time constant (filtering)	200ms (Flow); 200ms (Backscatter)
Display update time	2s (5s rolling averaged)
Probe identification	Automatic; monitor stores one-time calibration
Probe calibration	Factory or user-calibrated using Oxford Optronix motility standard
Probe shelf-life	Unlimited
Zeroing	Automatic, controlled
Default analogue data output range	0 - 5V (= 0 - 5000 BPU or 0 - 100% Backscatter)
Analogue data output rate	65 Hz

Table 7: OxyFlo technical specifications

7. 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.