Biochrom Libra S50, S60, S70 & S80

UV Visible Spectrophotometers

Health & Safety Manual

DECLARATION OF CONFORMITY

This is to certify that the following Biochrom manufactured products conform to the requirements of the following Directives -:

Biochrom Libra S50 (80-7000-00, 80-7000-01, 80-7000-02, 80-7000-03, 80-7000-04)
Biochrom Libra S60 (80-7000-10, 80-7000-11, 80-7000-12, 80-7000-13, 80-7000-14)
Biochrom Libra S70 (80-7000-20, 80-7000-21, 80-7000-22, 80-7000-23, 80-7000-24)
Biochrom Libra S80 (80-7000-30, 80-7000-31, 80-7000-32, 80-7000-33, 80-7000-34)

2006/95/EC	Low voltage equipment safety directive
98/79/EC	In Vitro Diagnostic Medical Devices Directive
2004/108/EC	EMC directive
2002/96/EC	EC Directive on Waste Electrical and Electronic Equipment (WEEE) 2003/108/EC & 2008/34/EC
2002/95/EC	Restrictions of the use of certain Hazardous Substances in Electrical and Electronic Equipment (ROHS)
2006/42/EC	Machinery directive
1999/5/EC	Radio and Telecommunications Terminal Equipment Directive (instruments fitted with Bluetooth accessory only)

Standards to which conformity is declared, where relevant, are as follows

EN61010-1:2001	Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements
EN61010-2-101:2002	Particular requirements for IVD medical equipment
EN61326-1:2006	Electromagnetic compatibility - generic emission standard electrical equipment for measurement, control & laboratory use.
EN12100-1,2:2003(+A1:2009)	Safety of machinery–Basic concepts, general principles for design
EN14121-1:2007	Safety of machinery, Risk assessment

For further information, including unpacking, positioning and installation of the products please refer to the user manual.

Signed:

Brian Clarkstone
Technical Director
Biochrom Ltd

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HEALTH & SAFETY

General safety

This equipment has been designed to conform to the following directives

2006/95/EC	Low Voltage Equipment Safety Directive
98/79/EC	In Vitro Diagnostic Medical Devices Directive
2004/108/EC	EMC Directive
2002/96/EC	EC Directive on Waste Electrical and Electronic Equipment (WEEE) 2003/108/EC, 2008/34/EC
2002/95/EC	Restrictions of the use of certain Hazardous Substances in electrical and electronic equipment (ROHS)
2006/42/EC	Machinery directive
1999/5/EC	Radio and Telecommunications terminal equipment directive (instruments fitted with Bluetooth accessory only)

Standards to which conformity is declared include

- EN61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use.
- EN 61010-2-101:2002 Particular requirements for IVD medical equipment
- EN 61326-1:2006 Electromagnetic compatibility - generic emission standard Electrical equipment for measurement, control and laboratory use. Classified as basic immunity criterion A and Class B for conducted and radiated emissions
- EN 12100-1,2:2003 (+A1:2009) Safety of machinery – Basic concepts, general principles for design
- EN 14121-1:2007 Safety of machinery, Risk assessment

General Hazards

There a number of warning labels and symbols on your instrument. These are there to inform you where a potential danger exists or particular caution is required. Before commencing installation, please take time to familiarise yourself with these symbols and their meaning.

This instrument is intended for use by individuals trained in and familiar with the use of spectrophotometers and their associated hazards. In the event of a malfunction or hazard occurring, the user responsible shall disconnect the unit from power and isolate for decontamination and /or repair.

This instrument is subject to the following hazards:

High voltages exist inside the unit. Repair and maintenance should only be carried out by individuals trained specifically to work on these instruments

The UV source contained within the unit generates a light beam that traverses the sample chamber and is accessible in the lamp chamber. Under normal use the lamp beam is confined within the instrument. The unit should not be operated with the sample chamber lid open or the lamp housing lid removed. Prolonged exposure to the beam may cause permanent eye damage.

There are no bio-hazardous materials within the unit; however this unit could be used with bio-hazardous samples. Before using the instrument the customer should have in place decontamination procedures designed to protect laboratory workers from occupationally acquired infections. The sample chamber cell holders are removable and may be decontaminated using the appropriate disinfectant for the bio hazard in question, rinsed with distilled water and then allowed to dry. The sample chamber and exterior may be wiped with a suitable disinfectant cleaning wipe.

- Decontamination. Equipment returned for repair should include an appropriate decontamination certificate
- It is the responsibility of the customer to ensure that the user of the equipment is provided with a safe working environment.
- Any chemicals used in Analyses should be used, stored and disposed of in accordance with manufacturer's guidelines and local safety regulations
- Toxic Fumes. Efficient laboratory ventilation must be provided when working with volatile solvents or toxic substances
- Waste disposal. Disposal of some solvents and chemicals may be classed as hazardous waste and must be dealt with in accordance with local regulatory practice.
- Personal protective equipment. This is not required to operate the unit but the samples measured may require PPE. A local risk assessment should be carried out.

This equipment may be connected and controlled from a PC. To preserve the integrity of the measuring equipment it is essential that the attached PC itself conforms to basic safety and EMC standards and is set up in accordance with the manufacturers' instructions. If in doubt consult the information that came with your PC. In common with all computer operation the following safety precautions are advised.

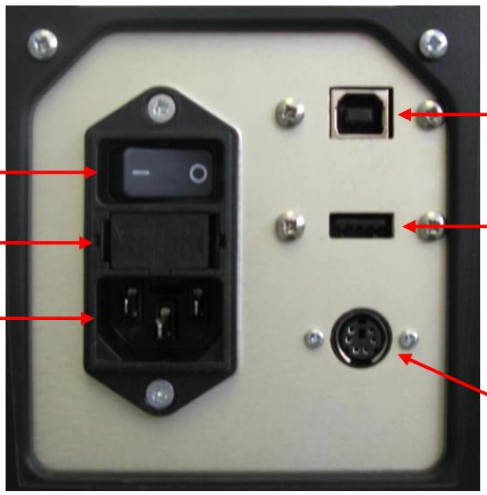
- To reduce the chance of eye strain, set up the PC display with the correct viewing position, free from glare and with appropriate brightness and contrast settings
- To reduce the chance of cross contamination from biological samples, use appropriate personnel protection measures and disinfectant wipes on keyboard and mouse.

Care must be taken when handling all heated accessories

Unpacking and Installation

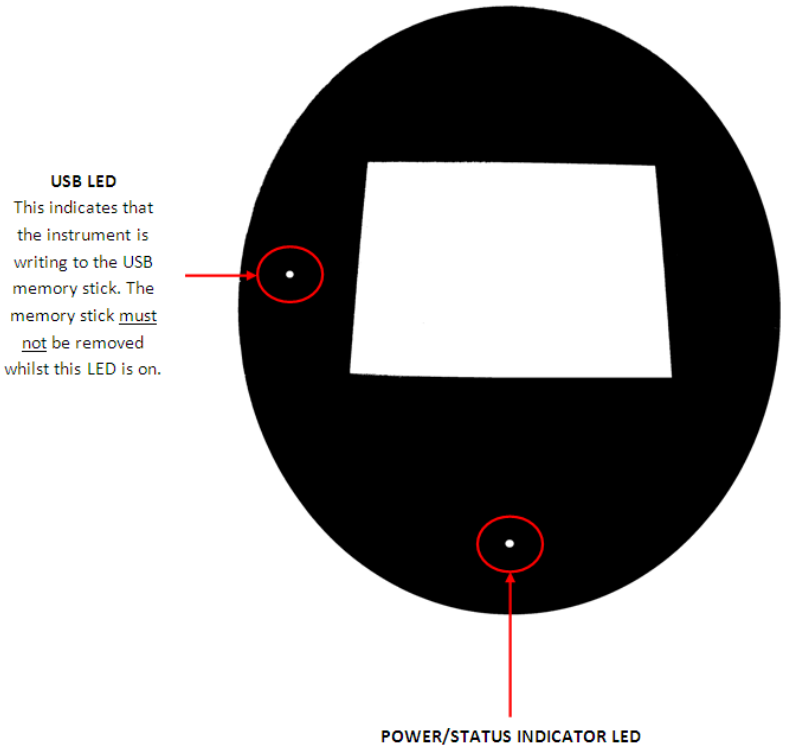
- These instruments weigh approximately 18.5kg. Follow you local regulations for safe handling and lifting of this equipment.
- Inspect the instrument for any signs of damage caused during transit. If any damage is discovered. Do not use the instrument and report the problem to your supplier.
- The instrument must be placed on a stable, level bench or table capable of taking its weight with sufficient space around the instrument for ventilation to circulate freely.
- Ensure your proposed installation site conforms to the environment conditions for safe operation
    - Indoor use
    - 5 to 40 °C
    - Maximum relative humidity 90% up to 31 °C decreasing linearly to 50% at 40 °C
- Extremes of temperature may require recalibration of the unit for optimum performance
- If the instrument has been stored in a cold environment then it should be allowed to come to thermal equilibrium for 2 to 3 hours before operation so that start up calibration is not compromised by condensation.
- The equipment must be connected to the local supply outlet using the provided power cables. It can be operated from 85 to 264 V~ 50 or 60 Hz.
- Replace power inlet fuses only with the same type and rating as follows
    - For Deuterium/Tungsten units T 1.6 A H 250 V AC (Anti-Surge, High breaking capacity)
    - For Xenon units T 1.6A H 250 V AC (Anti-Surge, High breaking capacity)
- Power rating is
    - 100 VA for Xenon units
    - 150 VA for Deuterium/Tungsten units
- The instrument should be positioned so that the power cable may be readily removed in the event of a hazard or malfunction occurring.
- Site the instrument in an atmosphere free from dust and corrosive fumes.
- Use the on/off switch on the left hand side of the instrument. The instrument will automatically perform some start up self diagnostic checks on switch on. Please wait for these to finish before attempting to use the equipment.

Instrument Connections



Equipment Operation

Controls and Indicators



INTENDED USERS

The instrument is intended to be used by scientists and technicians who possess basic laboratory and technical skills and have the knowledge and understanding of the hazards involved, with the unit and the samples used, to operate it in a safe manner.

Instrument Preparation

- Switch on the unit and allow it to finish its start up calibration
- Best performance is obtained if the instrument is allowed to warm up and stabilise for at least 30 minutes
- If applicable connect the unit to a PC using a USB cable and refer to the online help and user manual
- Select the appropriate application or method
- Where relevant, set up the application parameters for the sample
- For Deuterium/ Tungsten units a precision mode is available. To use this mode enter the desired application and switch to precision mode
- Select cuvette cells to use. It is important to use cells of the correct type. Most samples are measured using a standard 10mm path length cell. Special cells and accessories are available for larger or smaller path lengths and sample volumes. It is important to use cells of the

correct type. Some cells absorb in the UV and are not suitable for UV sample measurement. Cells used for samples should be free from dust, residue or scratches.

- Before preparing samples and sample reference blanks, you must be familiar with hazards arising from handling the sample materials and where necessary observe local regulatory practice, personnel protection equipment and measures designed to ensure your safety.
- Prepare the sample blanks (references). A reference is typically the solution that the sample is dissolved in. For Split beam models a reference is required. For Dual beam units the reference may be placed in the reference path or a separate sample reference may be made by first placing the reference in the sample path and performing a reference measurement.
- Prepare the sample solutions. The sample solution would normally comprise the sample under test dissolved in the reference solution
- When placing the cells in the equipment ensure the cell is orientated so that the light energy will pass through the cell
- For further information on running applications and methods refer to the user manual

Post Run procedures

- Empty cuvette cells of sample and rinse with deionised water
- Clean cuvettes periodically with commercially available cleaning solution or dilute detergent solution followed by a thorough rinse in deionised water.
- Note that some samples and solvents may be classified as hazardous or bio hazardous waste. The disposal of such substances must be carried out in accordance with local regulatory practice

Performance Validation

Good laboratory practice recommends that the unit is periodically checked for optical performance.

- Switch on validation checks. When the unit is powered up it performs wavelength accuracy and lamp energy checks. Once complete the unit will beep and show a green on light.
- Periodically wavelength, stray light and absorbance should be checked to ensure the unit is performing to specification. Deterioration in performance may indicate that the instrument needs servicing or that a poor baseline has been saved. Performance validation can b carried using traceable reference materials.

If the equipment is operated in a manner not specified, then the protection provided by the equipment may be impaired and the instrument warranty withdrawn.

User Maintenance

- Other than the Tungsten and Deuterium lamps in certain instruments there are no user serviceable parts in this equipment.
- To prevent contamination
  - Cell holders and accessories should be removed and cleaned with commercially available cleaning solution or dilute detergent followed by a through rinse in deionised water. Allow to dry thoroughly before use
  - Casework and the sample compartment may be wiped down with commercially available disinfectant wipes
- The lamps used in the unit age over time and less energy will be available to pass through the sample. Where energy has fallen to around 50% of the installation energy you are

advised to have the lamps changed. Deuterium and Tungsten lamps may be replaced by the user. Xenon lamp replacement can only be carried out by a qualified service engineer.

- To replace a Deuterium or Tungsten lamp ;
  - Switch the instrument off, disconnect the power supply cord and allow lamps to cool.
  - Locate the lamp access cover at the rear of unit and remove the two top screws and slide top cover back and lift off. Never operate the unit with the lamp housing cover removed.

  - Remove the lamp and dispose of in accordance with local regulatory practice.
  - Follow the handling instructions supplied with the lamp. Do not touch the glass envelopes of the replacement bulbs directly.
  - Replace the lamp cover and screw securely.
  - Attach power cord, switch on and wait at least 30 minutes for the unit to warm up.
  - Perform a new instrument baseline (on all bandwidth settings if variable bandwidth unit) and save this as the permanent baseline (see the online help or user manual).
  - Reset the lamp hours after replacing the lamp (see the online help or user manual).

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE
Start up calibration fails	Check sample (and reference) beam is clear before switch on Possible optical failure, contact service support
Negative absorbance reading	Check that sample and reference cells have not been swapped Check sufficient height of sample solution (beam height is nominally 15 mm above the cell base for normal measurements and it is recommended that it be filled to 20 mm above the base)
Unexpected results	Check for bubbles in solution
Absorbance values higher than expected	Check for use of incorrect cell type Check cells are free from finger prints Check cells for contamination Check cell orientation Check reference used Possible optical alignment problem, contact service support
Absorbance value lower than expected	Check sufficient height of sample solution Check sample and reference are not the same Check sample compartment lid is properly closed Possible stray light issue, contact service support
Instrument will not reference	Check orientation of cuvette Check for use of incorrect cell type
Poor reproducibility with nucleic acid analysis	Check for particles, try using background correction Try increase in concentration

Customer Support Contacts

Note: If you experience any problems with your instrument, please refer to the troubleshooting guide on page 8. If you require further assistance, please contact customer support at

http://www.biochrom.co.uk/content/1/11/support.html

Customer Support ROW	+44 (0)1223 427890	support@biochrom.co.uk
Customer Support US		support@biochrom.co.uk

Service, Repair or Return

Good laboratory practice recommends that the unit be periodically serviced to ensure the unit is suitable for purpose. It is recommended that the instrument be serviced annually. You can arrange this through your distributor. Prior to Inspection, Servicing, Repair or Return of Medical and Laboratory Equipment the unit must be decontaminated.

A returns policy operates on this equipment. Before returning the equipment to the distributor or manufacturer

- Fill in a returns request form. Available from the web site or your local distributor
- Return the unit together with a completed declaration of contamination status form. Available from the web site or your local distributor
- Please note that instrumentation will not be accepted for servicing or return until a completed declaration has been received
- Instrumentation that has not been cleaned sufficiently or decontaminated may be subject to additional charges and return delay

Disposal

Decontamination

In use this product may have been in contact with bio hazardous materials. Before disposal all accessories should be removed and thoroughly cleaned in disinfectant and then rinsed with distilled water. All outside surfaces and sample chamber walls must be wiped down with disinfectant wipes suitable for purpose

WEEE

A label with a crossed-out wheeled bin symbol indicates that the product is covered by the Waste Electrical and Electronic Equipment (WEEE) Directive and is not to be disposed of as unsorted municipal waste. Any products marked with this symbol must be collected separately and in accordance with local regulatory practice.