

In-Process Particle Size Analyser (Including IntelliSizer Options)

~ User Manual ~

Issue 15

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XO0XP User Manual

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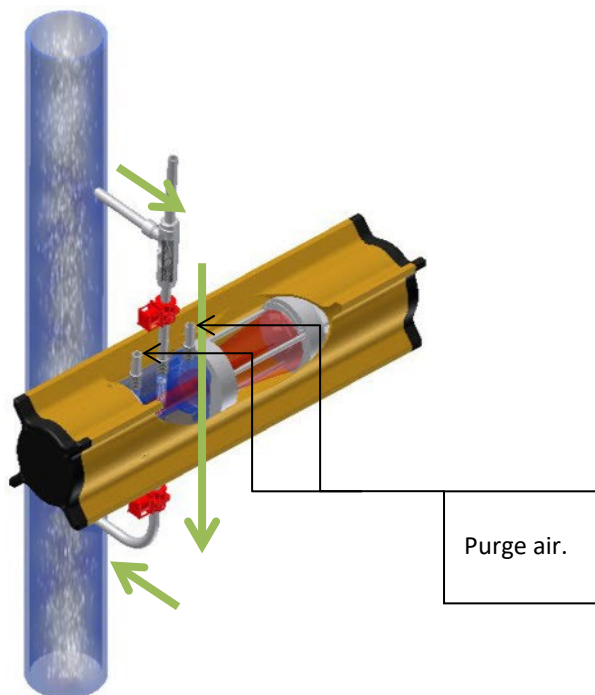
1 INTRODUCTION

1.1 System overview

The Xoptix in-process particle size analysers are part of a range of products from Xoptix to enable better understanding and control of industrial processes which involve the production of particulate material.

The system is designed to be easy to integrate, easy to set up, easy to use and provide the user with all the tools necessary to quickly understand the real-time distribution of particle size in their process.

The instrument has been developed from the XO series of in-process particle sizing analysers which are designed to sit permanently in industrial processes for continuous monitoring. A diagram of this is shown below:



The normal operation of the XO / XI particle size analyser is shown here, and is described as follows:

A continuous 'bleed' of sample is drawn from the process using the motive air of the venturi eductor pump.

The sample passes through the measurement unit where it is measured in real-time and returned to the process. The green arrows indicate the flow of the particles through the measurement head.

The purge air is designed to ensure that the optical path through the system stays clean.

Figure 1 - Measurement Method

The system is capable of measuring at up to 2000 times per second, but typically measurements are integrated over several seconds each, and run continuously to monitor the production process.

Some unique features, not shown in the previous picture, but key to the performance are:

1. Additional sheath air control which ensures the particles are properly entrained in the measurement region as they pass through the sample cell.
2. Unique cell clean function, which can be fully automated to ensure continuous operation of the system in the process.
3. 'Hot swappable' sample cell. The system has been designed so the sample cell can be removed and replaced in less than 1 minute without disturbing the alignment.
4. Local display of any size parameters and sample loading through the instrument which gives the user maximum information of their process.

With all Xoptix systems the external requirements are the following:

- Clean dry oil free air.
- A computer running at least Microsoft Windows 7.

If the sample is not returned to the process the following is also required:

- An extraction system to remove the sample from the system.

More details on the specification of these will be discussed later in this manual.

1.2 Scope of this manual

This manual is a generic manual for all Xoptix dry particle sizers (excluding PharmaSizer). Hence, some pictures might not exactly match the model you have. However, the principles are identical.

This manual does not cover installation and setup of the instrument. Reference should be made to the Installation Manual where this information is required.

2 HEALTH AND SAFETY

2.1 Site requirements

The system has specific site requirements that must be enforced to ensure the safe operation of the instrument. Information on site requirements can be found in section 'Site requirements' on page 9.

2.2 Sample handling considerations

Always ensure that all substances are handled in accordance with the COSHH (Control of Substances Hazardous to Health) regulations (U.K.) or any local regulations concerning safety of sample handling.

Always check the MSDS (Material Safety Data Sheets) before handling any substances and follow all instructions carefully.

Do not smoke or eat during measurement procedures, particularly where inflammable or toxic sample are used or stored.

If hazardous samples have been measured, scrupulously clean the system to remove any traces of those samples before making another measurement.

2.3 Laser safety warnings

The XO/XI is a class 1M laser product in normal operation. The laser is transmitted through the measurement zone during measurement. During normal operation, there is no exposure to laser radiation (when the cell is secure in the sizer). If the cell is removed from the instrument, the covers removed or the sizer is dismantled for maintenance then the laser may be visible. A class 1M laser is safe for all conditions of use except when passed through magnifying optics such as microscopes and telescopes.

DO NOT disassemble the transmitter assembly, doing so will change the classification of the laser.

2.4 Earthing considerations

This product is fitted with a protective earth connection. Never run the equipment without a protective earth connection. This is important for the safe operation of the equipment and to ensure that there is no build-up of static electricity due to the flow of powder through the system.

2.5 General Assembly

During assembly and dis-assembly for general maintenance the user should take care to handle all parts carefully as some of the parts including the "Flow Conditioning Module" and the "Sample Cell" are heavy and could cause injury if mishandled.

Additionally, no maintenance should be done until the air and electrical supplies have been isolated

2.6 ATEX/UKEX Considerations

The XI and XP Ranges of In Process Particle Size analysers are manufactured from either an aluminium or stainless steel enclosure, with includes one or more of the following O-ring seal materials that are relied on for safe operation:

- Silicone / Nitrile / Perfluoroelastomer

These materials and parts may be damaged by aggressive environments and the chemical compatibility needs to be considered before use. If the In Process Particle Size analysers are to be located in an environment that may damage these material/parts, contact Xoptix Ltd before installation.

3 SITE REQUIREMENTS

3.1 Introduction

The following is a detailed discussion of all requirements for the proper installation and operation of the XO/XI instruments. This section should be read carefully in conjunction with the Installation Manual before attempting to install the instrument.

The general requirements are duplicated here to ensure safe operation is maintained after installation.

Please Note:

Failure to observe any of the site requirements, or to modify the instrument in any way, or to neglect to correctly connect the instrument to its power supplies and to ensure adequate earthing could compromise its performance as certified for CE and ATEX/UKEX.

3.2 General requirements

When choosing a site for the system, ensure that the following conditions are satisfied.

1. Ensure the instrument is positioned away from strong heat sources including direct sunlight.
2. Do not obstruct power supplies, air hoses or signal cables as they may need to be disconnected during an emergency.
3. Never allow electrical cables to pass through areas where liquids can be spilt.
4. The sizing unit should be permanently mounted using the brackets supplied on a solid surface with minimal vibration to ensure stability of measuring platform.
5. Enough space should be allowed to give easy access to all parts of the system.

3.3 Operating conditions

The system has been designed to be operated in the following conditions:

Temperature: -10°C to +50°C.

Humidity: 10% to 90% (non-condensing).

Please note it should be realised that whilst the equipment can operate in this range, accurate measurements are dependent on the sample being “dry”. For example, dry powders may stick together in high humidity, rendering practical measurement very difficult.

Space: Enough to allow easy access to all components of the system.

3.4 Dimensions

When fully assembled, the XOOXP unit occupies a volume of approximately:

	Length (mm)	Depth (mm)	Height (mm)
XO220P	460 (510)	140	550
XO550P	620 (670)	140	550
XO1100P	890 (940)	140	550
XI220P	470 (520)	140	550
XI550P	630 (680)	140	550
XI1100P	900 (950)	140	550

Note: Allow an extra 50mm length on each of them for the Lemo connector (shown in brackets in the table).

It should be mounted in such a manner that all parts can be safely accessed for routine maintenance and safe operation.

3.5.1 Air (gas) supply

The motive and purge gas should be clean and free of any moisture and oil. Regardless of conditioning units on a factory compressed air system we recommend that a high-quality trap/filter element is installed just prior to the air feed for the equipment.

If compressed air is being used it should conform to the following specifications:

- Maximum particle size: 0.1microns.
- Maximum particle concentration: 0.1mg/m³.
- Maximum oil concentration: 0.1mg/m³.
- Gas supply pressure: 4 to 6 bar (58psi - 87psi).
- Gas supply flow rate: 300 l/min (18m³/hr or 636 cf/hr).

3.5.2 Power specification

The consideration for supply of power is related to the sizer only as the computer used by the sizer will have its own power considerations.

The sizer installation requires a clean filtered regulated DC supply of 24V capable of supplying 5 amps.

The equipment must be earthed.

3.5.3 Computer specification – Single instrument

The computer on which the XO/XI software is installed should have at least the following specification:

- Processor: At least Intel Core i5 or equivalent.
- Memory: At least 4GB.
- Hard Disk: At least 1TB.
- CD-ROM.
- 9-way RS-422 port.
- Supported operating systems: Windows 7, Windows 10.

The above specification assumes only one instrument is being run by the computer. Where multiple instruments are being run on the same computer it is recommended that a multi core processor is used with 1 core for each instrument i.e. If 4 instruments are being run then a quad core processor is recommended.

For multi-tasking, more memory is also required.

3.5.4 Computer specification – Multi instrument

The minimum computer specification for multiple (maximum of 4) instruments running on a single system is:

- Processor: Quad core 2.5GHz.
- Memory: 8GB.
- Hard Disk: 1TB.
- CD-ROM.
- One 9-way RS-422 port for each instrument. Where these are PCI or PCIe based it is recommended that a single card multi-port option is used.
- Supported operating systems: Windows 7, Windows 10.

It is the responsibility of the user to ensure that a backup protocol is implemented to ensure that there is no loss of data in the event of system failure.

4 SETTING UP THE SYSTEM FOR MEASUREMENT

4.1 Introduction

This section assumes that the system has been installed by a qualified engineer.

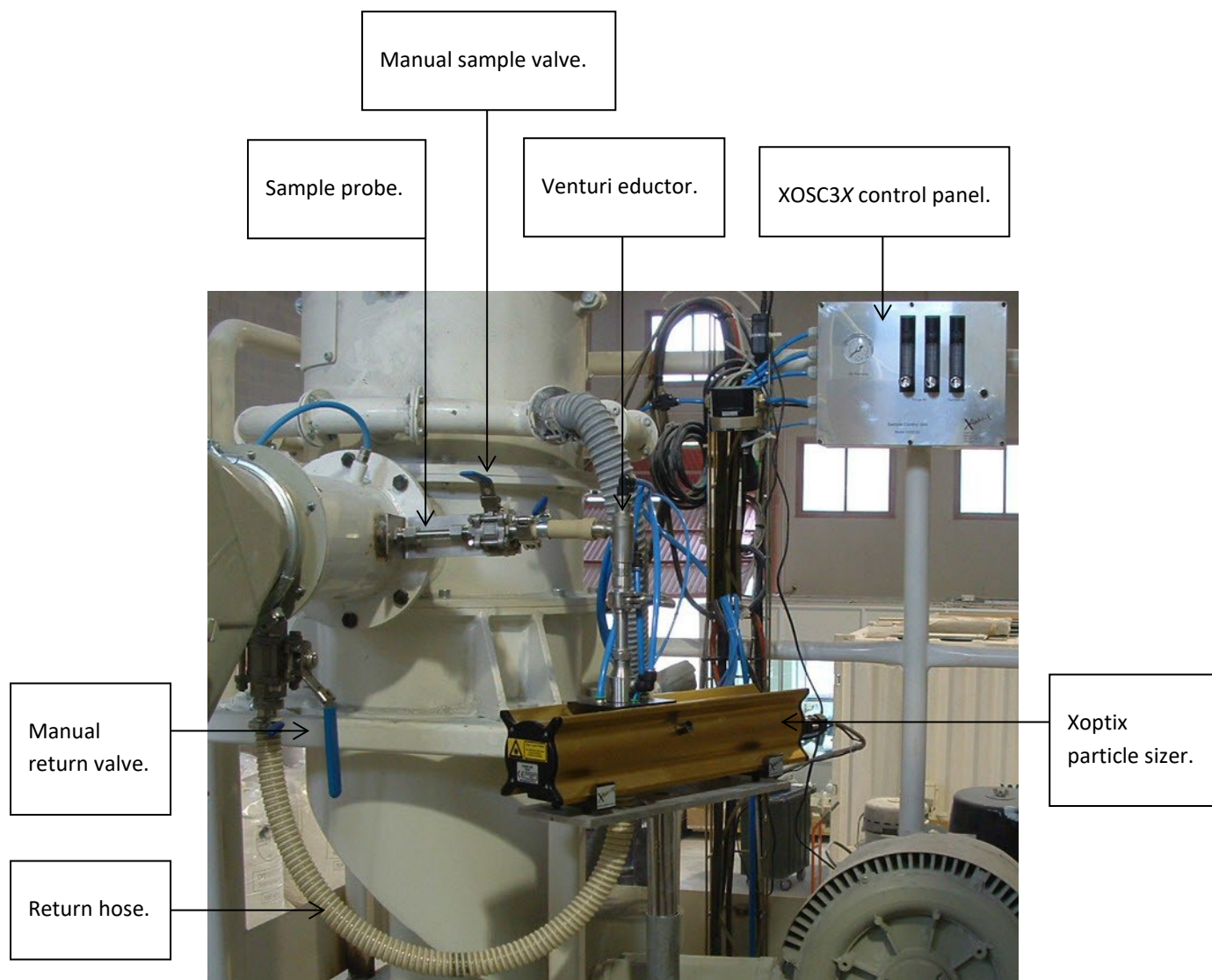
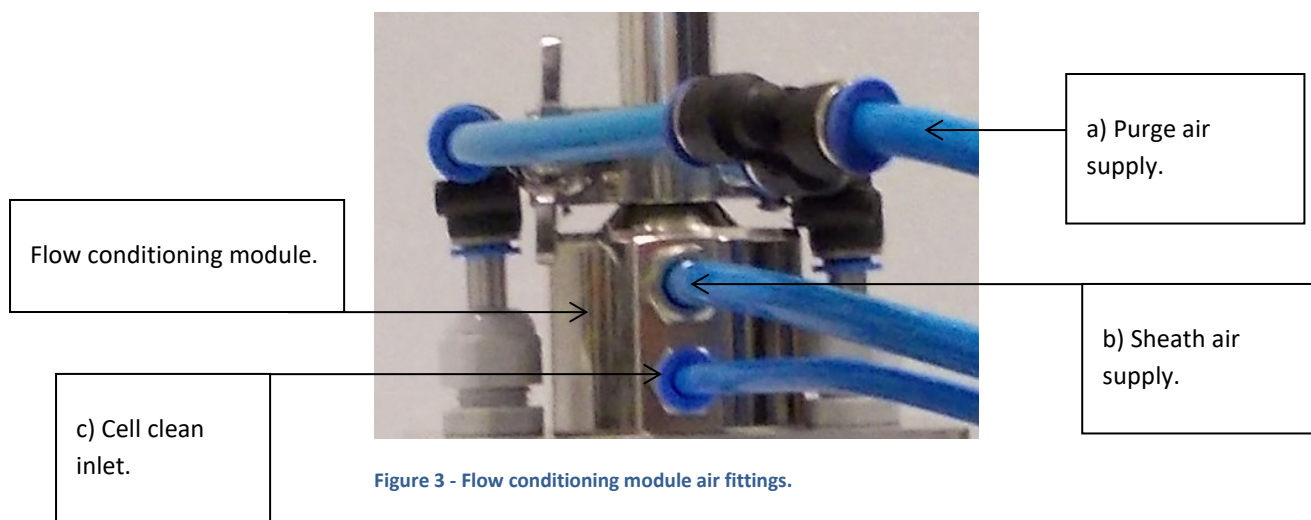


Figure 2 - A typical manual installation.

Automatic systems may have additional pneumatically or electrically operated sample and sample return air valves.



This shows an enlargement of the flow conditioning module which is fixed to the cell top. The cell clean, purge air and sheath air pneumatic fittings are also shown.

- a) Purge air – This allows a constant stream of air to blow particles away from the cell windows to keep them clean.
- b) Sheath air – This is also to prevent particles dirtying the dry flow cell windows and produces a sheath of air to entrain the particle in a tight jet passing through the laser beam.
- c) Cell clean inlet – If any dust does settle on the cell windows, this allows the dust to be removed with a jet of compressed air passed over the cell windows.

4.2 Connecting the cell assembly

This section of the manual will guide the user through the connection of the pneumatic pipes and the flow conditioning module.

In standard practice, the flow conditioning module does not require removal unless all the seals are being checked and/or replaced.

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings, or any disassembly of the system is carried out, that the air supply to the system is switched off and under no pressure.


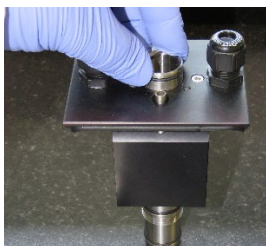
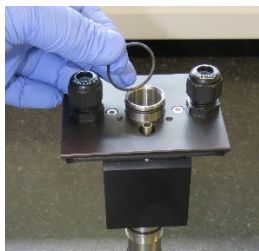

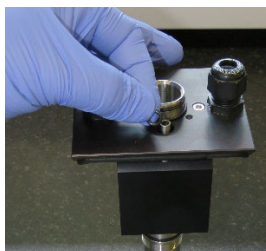
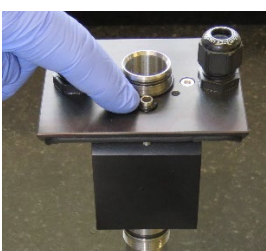

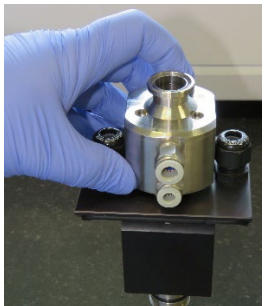
The above warning will be repeated throughout the manual for the safety of the user.

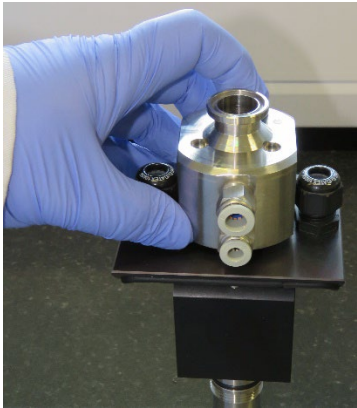
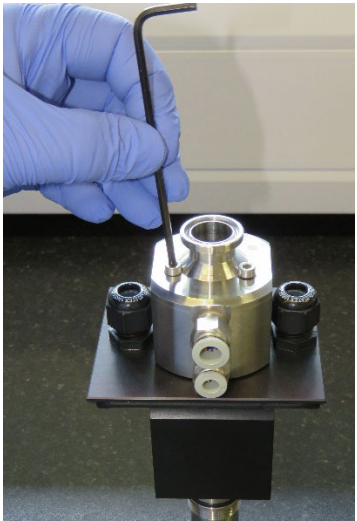

Below are step by step guides to connecting the cell clean, sheath, purge pipes and the flow conditioning module.

4.2.1 Connecting the flow conditioning module

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

If a cell has been disassembled then the flow conditioning module needs to be bolted back onto the cell top. To secure the flow conditioning module back onto the cell top please follow these instructions:

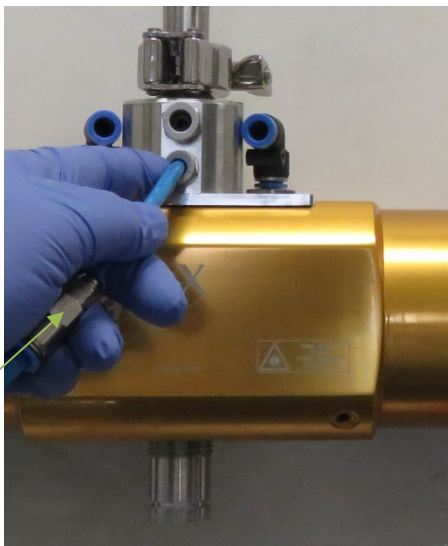
		1. Ensure the O-ring is present in the groove around the cell inlet and undamaged.
		2. Make sure the O-ring is present around the bottom of the cell inlet sitting on top of the cell top.
		3. Check the O-ring is in the groove at the bottom of the cell clean pipe.
		4. Line up the cell clean pipe with the smaller vacant hole on the bottom of the flow conditioning module and the cell inlet with the larger vacant hole on the bottom of the flow conditioning module.

	<p>5. Gently push down making sure not to damage any O-rings.</p>
	<p>6. Insert and tighten the 3 screws into the flow conditioning module.</p>
	<p>7. Note the gap at the bottom of the flow conditioning module should be almost non-existent when fully tightened.</p>

4.2.2 Connecting the cell clean

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

- a) Simply push the 6mm pneumatic pipe into the 6mm air fitting fixed in the flow conditioning module (the lower connector shown in Fig 3).
- b) (Optional) If the cell clean adapter had previously been disconnected, reconnect the cell clean adapter.

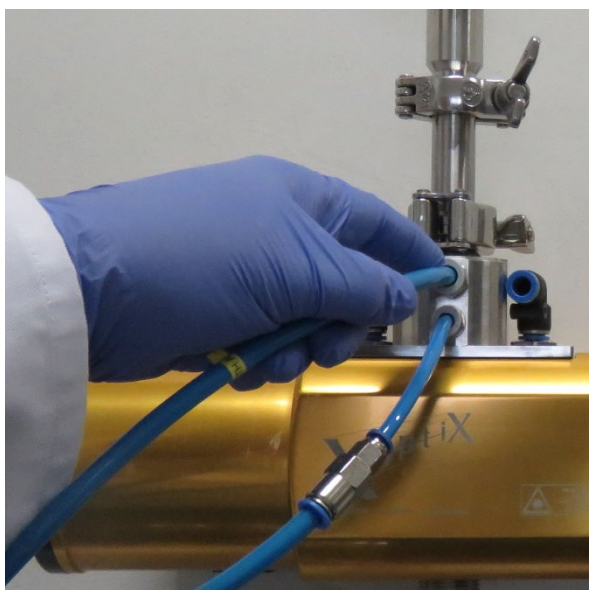


Note: The cell clean adapter is an air fitting allowing an 8mm pipe to be connected to 6mm pipe fitted prior to connecting to the flow conditioning module.

4.2.3 Connecting the sheath air supply

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

- a) Push the 8mm pneumatic pipe from the sheath air supply into the air fitting located in the highest position on the flow conditioning module.



4.2.4 Connecting the purge pipes

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

- Push the 8mm pneumatic elbow connectors onto the purge pipes ensuring a good seal has been made.
- Connect the purge air supply to the single end of the 8mm Y-connector.



a)



a)

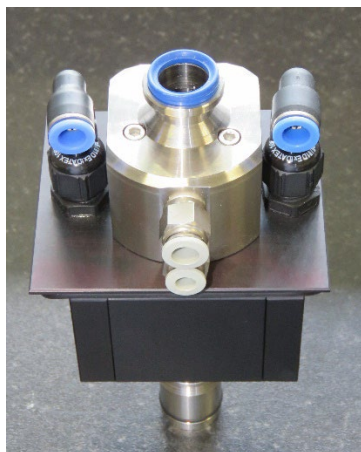


b)

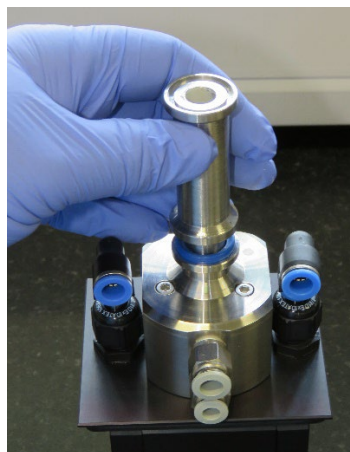
4.2.5 Secure the dry flow cell nozzle

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

- Place the $\frac{3}{4}$ " tri-clamp seal onto the groove in the flow conditioning module.
- Carefully slide the dry flow cell nozzle down until it is sitting on the seal on top of the Flow Conditioning Module.
- Use a tri-clamp to tighten the two pieces together securely.



a)



b)



c)

4.2.6 Connecting and securing the eductor

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

- Place the $\frac{1}{2}$ " tri-clamp seal on the sealing groove at the top of the dry flow cell nozzle.
- Carefully holding the eductor, ensuring not to drop it as it is quite heavy.
- Fix it to the dry flow cell nozzle using a tri-clamp ensuring it is tight and secure.
- Push the 8mm pneumatic pipe from the sample air supply into the air fitting at the top of the eductor.
- Push the decoupling hose leading from the sample air valve onto the eductor coupling, securing it with the hose clamp (21-23mm).



a)



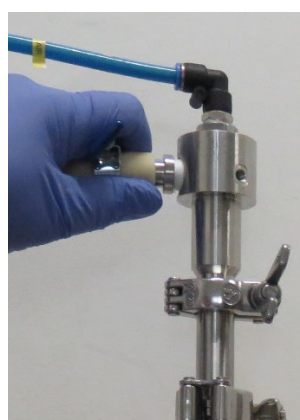
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c)



d)



e)

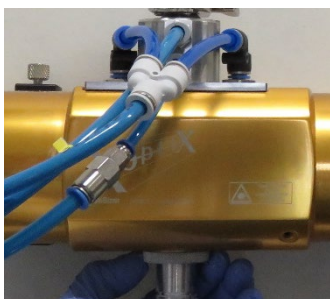


e)

4.2.7 Connecting the anti-static exhaust hose.

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

- a) Ensure the cell is placed within the sizer.
- b) Screw the dry flow cell retaining screw on the bottom of the cell ensuring it makes metal to metal contact with the pins on the bottom of the sizer for grounding purposes.
- c) Ensure a stripped part of the anti-static wire coil from the hose is tucked inside the hose end making sure it will make good contact with the cell outlet once pushed on.
- d) Place the hose clamp (size varies dependant on exhaust option) over the hose.
- e) Carefully push the anti-static hose over the cell outlet keeping the stripped wire on the inside, making sure not to displace any O-rings.
- f) Place the hose clamp over the hose at the top and ensure that the pipe is pushed as high up as possible.
- g) Tighten the hose clamp to ensure the hose is securely attached.



b)



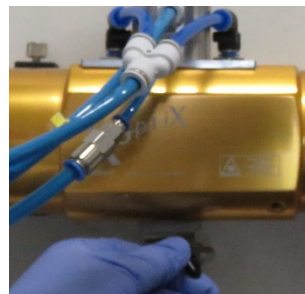
c)



e)



f)



g)

5 GENERAL OPERATION

5.1 Introduction

Although at first sight the operation of the system can seem quite complex, in reality once it has been set up, operation is simply a matter of turning the system on and running pre-programmed sequences.

Set-up of the sequences is discussed in section 'Software Operation' of this manual. This section discusses normal day to day running. Once familiar with the procedure the user should be able to go from off to fully set up for a measurement in only a few minutes.

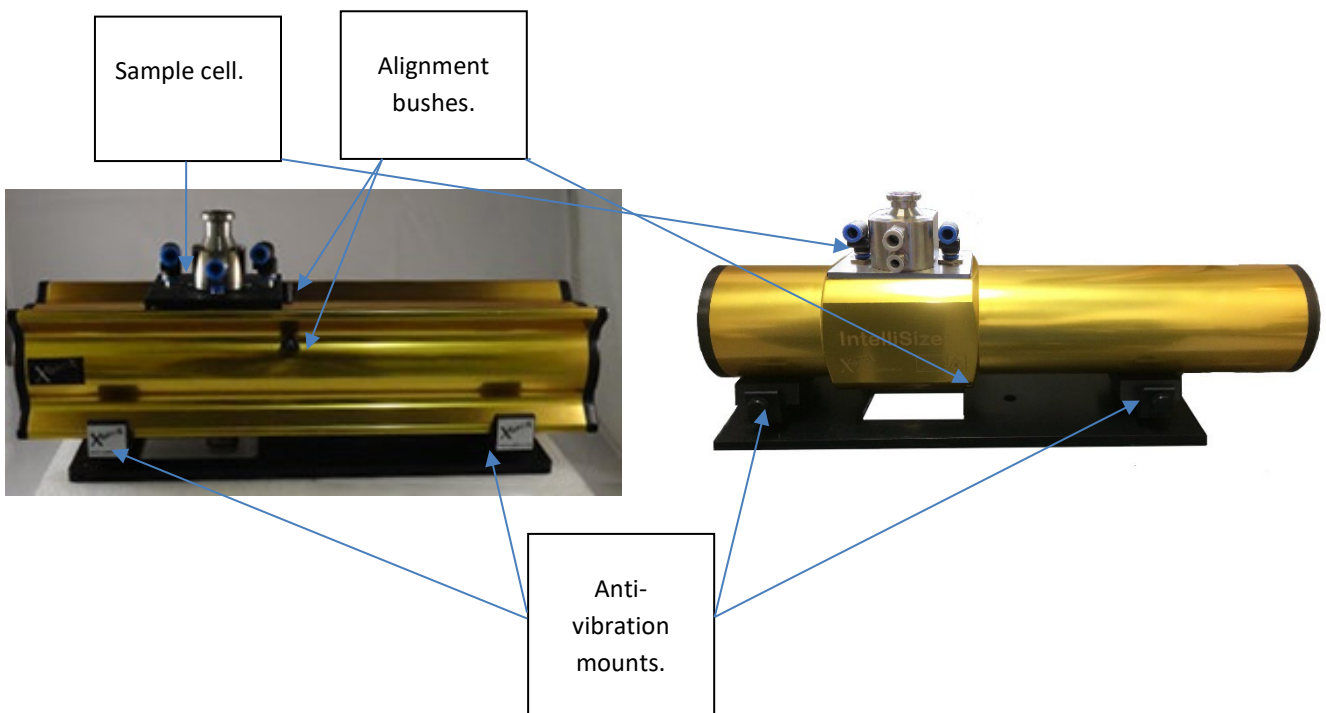
Despite the ease of use, each part of the system should be fully understood to ensure correct and safe operation therefore, the entire procedure should be understood.

Important: Do not switch on the sizer until all sample connections have been checked. This includes all valves and connections to the XOSC3X control box. If automated valves are used check all the electrical and air connections leading to the valves.

5.2 Key parts of sizer

The following parts of the sizer are considered key areas for the user to understand to ensure safe and successful measurements are made:



- Communication cable between the control unit or PC and the sizer.
- Sample cell.
- Alignment bushes.
- Anti-vibration mounts).



Before starting any measurements make sure the communication cable is securely plugged in, the sample cell is tightened down and fully connected and the anti-vibration mounts are tight and secure.

5.3 Normal operating procedure

Before operating the sizer to take measurements ensure the following actions are carried out:

1. Check the valve and cell connections for leaks.
2. Switch the system on and check the display on the sizer. The display on the sizer should illuminate and show text dependant on what actions the sizer is currently carrying out. The display should never be blank (some versions of the sizer do not come with an LCD such as the PharmaSizer and ATEX/UKEX options).
3. Switch the computer on and load the Xoptix sizer software.
4. Enter alignment mode by pressing the button ().
5. Inspect the background levels, re-aligning if necessary to get the first two channels to a minimum but similar level while keeping the laser level above 60%. For a more detailed explanation check section 'Routine Maintenance' of this manual.
6. Start the measurement procedure:
 - a. **Manual measurement:** This is where each individual stage is carried out by the operator, e.g. the operator carries out a background measurement followed by a manual or automatic (from the computer console) operation of the valves to introduce sample, followed by a manual sample measurement. This type of measurement is typically done to establish good measurement protocol.
 - b. **Automatic measurement:** This is simply done by clicking the "Run Sequence" buttons  in the software. These buttons automatically run a pre-programmed sequence for a fully automated measurement. Sequences are explained in the section 7.4.4.
7. The system is stopped by pressing the "Stop" button in the software or if the software was carrying out a single shot sequence that has finished. By clicking the exit button or the "x" in the top right of the software and following the on-screen instructions on the computer the software is then shut down. A "Safe Stop" sequence should be assigned to the "Stop" button ensuring key valves are switched into the correct position for when no measurement is taking place. For further information see the sequences explanations in section 'Setting up sequences' and 'Sequence and Triggers' in the Software Manual.
8. Switch off the computer.
9. Switch off the sizer.
10. Ensure all valves and services are isolated and safe.

6 THE XOSC3X SAMPLE CONTROL UNIT

SAFETY WARNING: Only qualified personnel should be involved with wiring inside the control box.

SAFETY WARNING: Before opening the control box for any reason ensure the air and electricity supplies are switched off and the control unit is depressurised.

6.1 Overview

The sample control unit handles all of the pneumatic and electrical connections to the particle sizer. The unit acts as the interim between the computer, sizer and air supply. Valves inside the control unit can be set up to toggle within the sizer software (explained later in the manual). The flow of the air allowed through each section of the control box (purge, sheath, sample and [optional] probe) can be adjusted using a 2mm Allen key.



Figure 4 - XOSC36 control unit

The box must be supplied with the following:

- Power:
 - 24V dc at 5amps.
- Air:
 - Clean dry compressed air.
 - Between 4 and 6 bar of pressure.

Note: The maximum standing pressure for the control unit is 6.8 bar.

Whilst the system is running measurements the control unit can be set up to display certain values on the LCD within the software (see section 'Valve Board Display' located in the "Software Manual" document for more information on how to do this).

6.2 Electrical connections

SAFETY WARNING: Only qualified personnel should open the inside of the box.

The electrical connections are fed through the cable glands at the bottom of the control unit. Inside the control unit several unpopulated terminal blocks are supplied to allow for easy fitting of electrical connections.

Note: When the XOSC3X is supplied, the cable for connecting the sizer is included.

Note: The cable for connecting the computer to the control box is not included as the wiring varies dependant on what interface is used.

Note: Unused glands need to be blocked off to maintain the IP seal of the control unit.

Upon opening the box with the supplied key, the user is presented with a diagram (see figure 5) showing where each connection is on the circuit board.

Note: The issue of PCB may differ with the image shown below, please check the supplied diagram on the inside sealing door for the correct version.

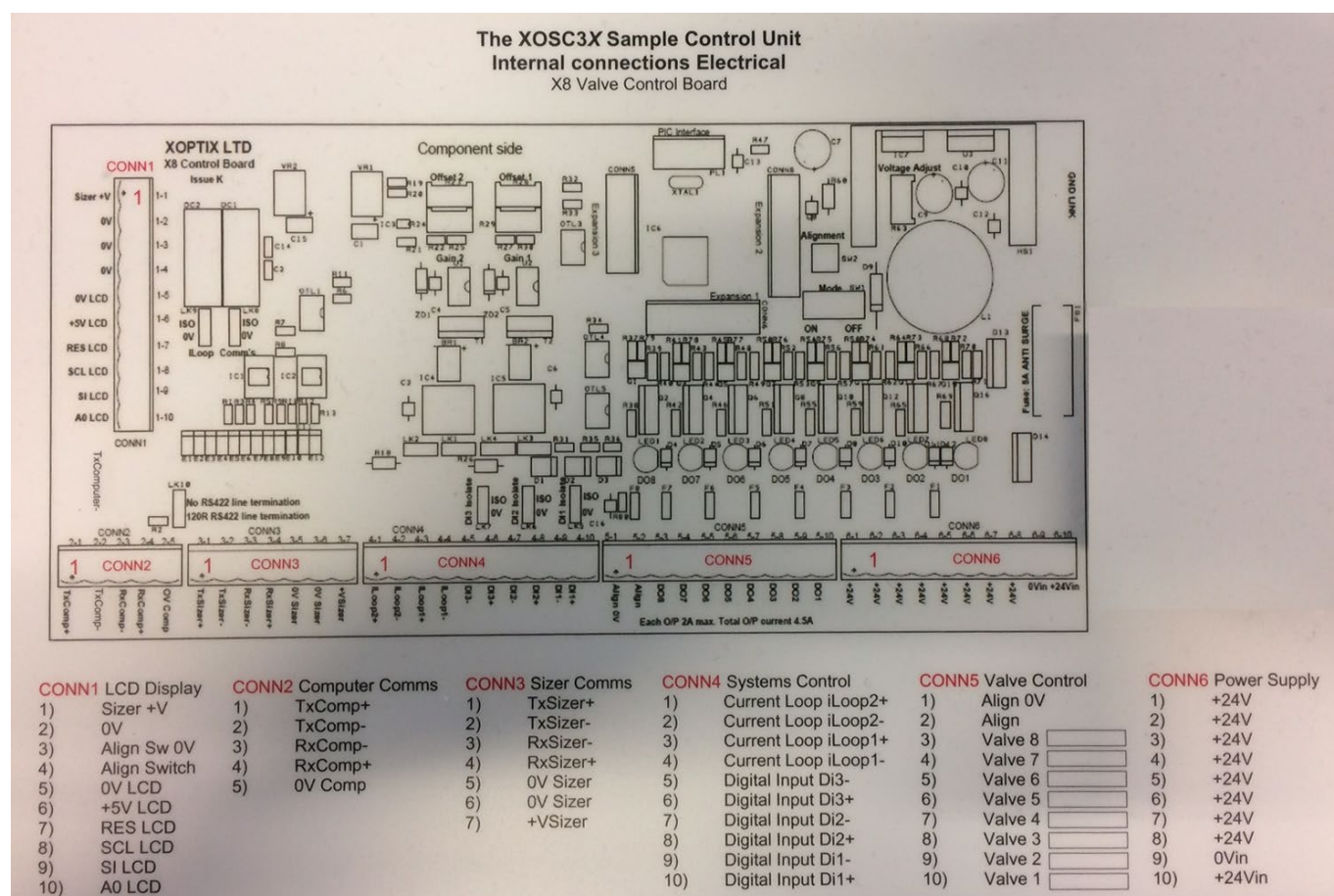


Figure 5 - XOSC3X connections (diagram)

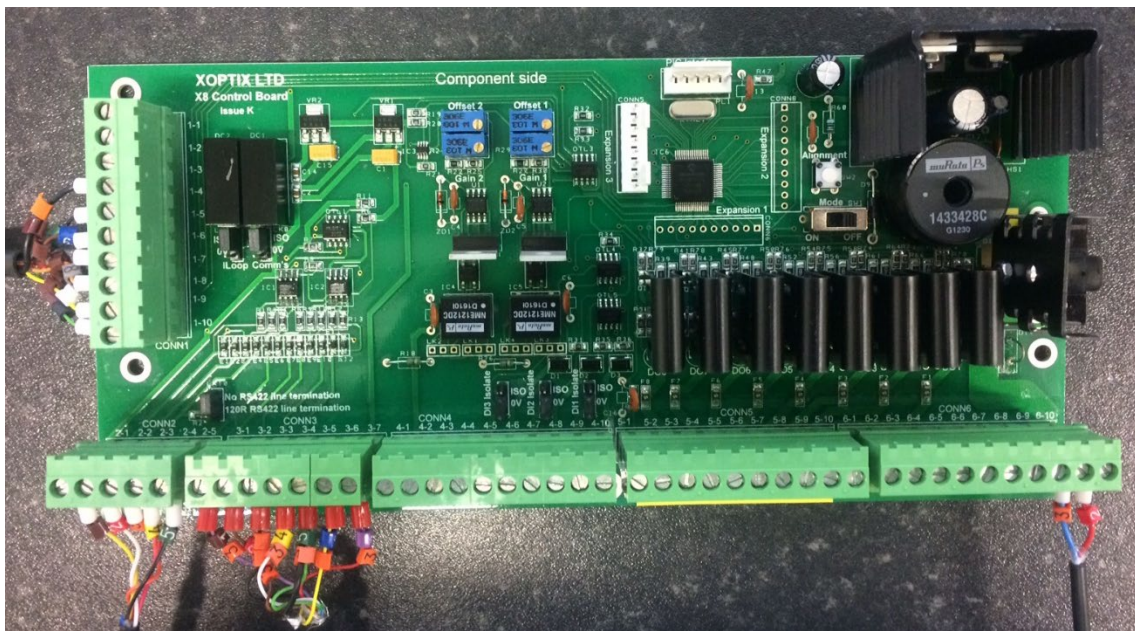


Figure 6 - XOSC3X connections photograph.

To add digital inputs or valves simply follow these instructions:

1. Locate the relevant terminal block shown on the diagram.
2. Pull the terminal block out of its socket.
3. Thread the wire up through the cable gland from outside the box.
4. Screw the wire into their appropriate location on the terminal block.
5. Plug the terminal block back into the PCB.
6. Gently pull out any excess wire from the cable gland making sure not to tug any wires out of the terminal blocks.
7. Tighten the cable gland.

6.3 Setting the air flow levels

To get optimum sizing accuracy and stability of measurement, the air flow settings of the purge, sheath and sample air flow meters need to be correctly set.

Note: This should have been done at installation but may need some customer adjustment where sampling conditions have changed, e.g. where different types or grades of material are being measured.

The following are the nominal settings for the flow meters (where no probe air is supplied):

- Purge Air: >100% of the full scale.
- Sheath Air: 40-50% of full scale.
- Sample Air: 30-50% of full scale.

For normal operation, the purge air and sheath air will not need to be adjusted from these settings (or the settings set up on commissioning).

The sample air may need to be adjusted to change the concentration of sample going through the sizer. A low sample air setting of around 30% of the full scale will give a low concentration going through the sizer while a high sample air setting of 50% or greater will give a high concentration going through the sizer.

Note: It may not be possible to achieve above 50% sample air.

A target for the sample loading to get through the sizer is between 15-20%, this may vary depending on the type of material and the particle distribution. For further advice contact your Xoptix representative.

Important: The air supply must be able to sustain an air pressure of at least 4 bar when the flow meters are at their operational settings. Operational air pressure is important, not the static air pressure. If the pressure drops below 4 bar the particle dispersion will be less efficient and the results will become unstable.

6.4 Boot up

When the control unit is booting up the LCD display will show the following (version/LCD may vary):



Figure 7 - LCD initialisation

The LCD display will continue to appear this way until a sizer is connected and the software is launched.

When the software is running and a measurement has been complete the display will change to show the last result, see figure 8. The results displayed on the LCD are user selectable via the software (refer to the Software Manual for more information):



Figure 8 – Result Displayed.

6.5 Alignment mode

Pressing the alignment mode button (fig 4) switches the control box into alignment mode. This means the LCD display will change to represent what the detector is seeing from the sizer.

Note: The values on the LCD during alignment mode will differ from those in the software as the linearity of the system is not imposed.

Alignment mode gives the user the option of aligning the system without the need of a local computer. Upon pressing the alignment mode button once the user will be presented with the following information on the LCD display:

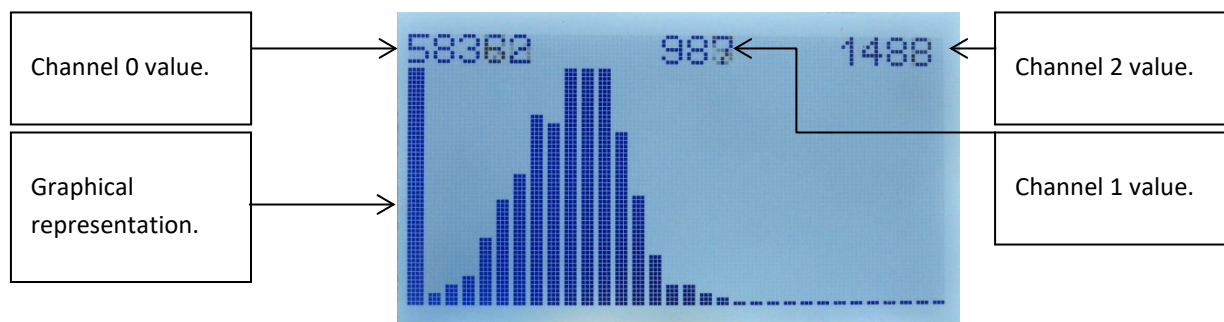


Figure 9 - Alignment mode.

The LCD display will adjust in real time giving the user instant feedback.

To exit alignment mode simply press the alignment mode button on the underside of the control box again and the LCD display will return to the default view. If the system is left in alignment mode for a prolonged period of time it will reset to the default view by itself.

6.6 Timeout

If the control box has received no information over a period of 10 minutes from the sizer software then the LCD will reset the displayed results to zero. This is to prevent the user from being misinformed that a measurement is taking place correctly when in fact the control box is not receiving new results.

7 SOFTWARE OPERATION

7.1 Software Installation

Place the Xoptix application CD-ROM into the CD drive on the computer and follow the on-screen instructions.

7.2 Preparation

Before running the software check the following:

- Check the sizer is connected to the control unit (where applicable).
- Check the sizer is powered.
- Check the control unit (where applicable) is connected to the computer.

On boot-up the Xoptix size monitoring system software will automatically detect the particle sizer, configure the serial port, turn on the laser and download the systems linearity files from the optics.

This section will cover the basic functions of the software, for more in-depth explanations of every feature in the software please refer to the Software Manual for more in-depth information.

7.3 Launching the software

To launch the software, locate the “Xoptix Sizer Monitor.exe” icon on the desktop and double click the icon. Alternatively locate the Xoptix Sizer folder in the start menu and click the shortcut within.

Once the software has been opened, a splash screen will show up displaying the current status of the software launch process, detecting the COM port the sizer is present on, the date of the software build and the software version.



Figure 10 - Splash screen.

If the sizer or control unit is not detected the following dialogue box will pop up:

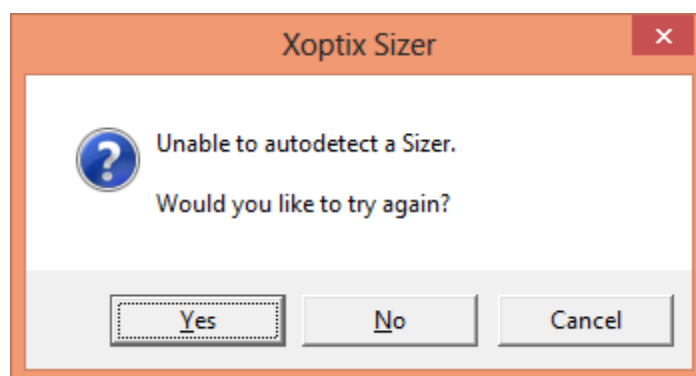


Figure 11 - Sizer not connected.

The available options carry out the following actions:

- Yes: Attempts to detect the sizer again.
- No: Launches the software without a sizer or control unit connected.
- Cancel: Cancels the software loading, closing the "Xoptix Sizer.exe" process.

If it is unexpected for the sizer not to be connected check all connections and power supplies observing safety procedures.

Once the sizer has been successfully detected and initialised (or the user launched the software with no sizer/control unit connected) the splash screen will disappear and the "Parameters" page will be displayed.

7.4 Preparing a measurement

7.4.1 Parameters set up

Before any measurement is carried out the parameters page must be set up. Below is a short description of what each parameter is for:

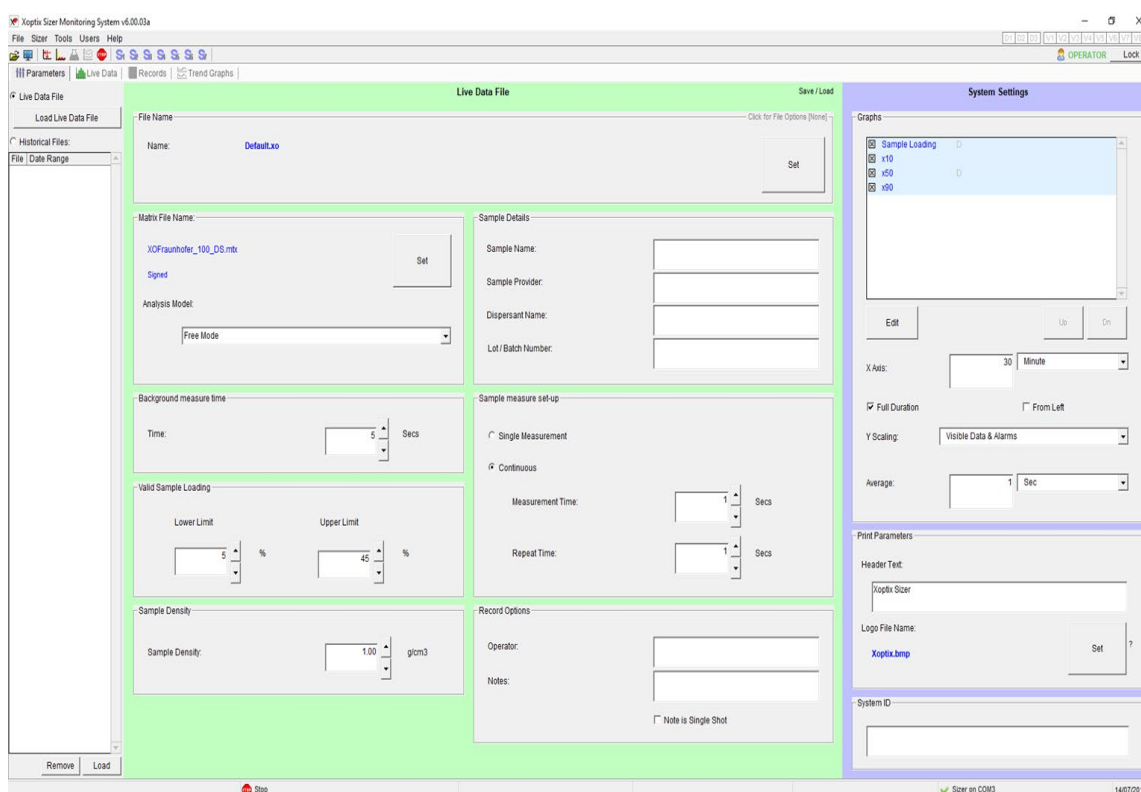


Figure 12 – Parameters Page.

- File Name:
 - Sets the file name for the measurement data.
 - Sets the location where the measurement data will be saved.
- File Options:
 - Allows a file name increment to automatically be carried out based on the date of the file.
 - Gives the additional option of outputting the data to a CSV (comma separated values) file in the same location as the data file.
- Matrix File Name:
 - Sets the matrix to be used to calculate the particle size from the light scattering data. The matrix used is changed dependant on what is being measured. A default Fraunhofer matrix is supplied with the application software, for applications which require Mie analysis, matrix files can be requested for any material from Xoptix.
- Analysis Model:
 - Offers a choice of various analysis models, the “Very Polydisperse” options are for when the dispersion of the material being measured contain particles that go beyond the size range of the instrument.
- Background measure time:
 - Sets the time period for a background measurement.
- Single Measurement:
 - When a measurement is made only one measurement will be recorded.
- Continuous measurement:
 - When a measurement is carried out it will continue to make measurements until the software receives a “Stop” command.
- Measurement time:
 - The period over which the sizer will gather measurement data.
- Repeat time:
 - During a continuous measurement, this is how often the system carries out a new measurement from the start of the previous measurement (e.g. a 5 second measurement with a 6 second repeat time will always start 1 second after that previous measurement has finished).
 - The repeat time also acts as the data save interval.
- Operator:
 - Text box to state the identity of the operator at the time of the measurements.
 - This is saved with each individual record.
- Notes:
 - Allows notes to be added before and during measurements.
 - Notes are saved with individual records.
 - If the single shot box is ticked this will just record the note once then clear the field.
- Sample details:
 - A section to fill in the sample information.
- Valid sample loading:
 - Sets the limits for what is considered “good data”, anything outside of these two limits is considered “bad data”. Despite being labelled ‘bad data’, this data is still stored as normal data, so it can be retrieved and examined later. Therefore, “bad data” can be toggled to be included or excluded from the records and graphs.
- Sample Density:
 - Allows the operator to set the density value of the sample being measured.
 - Used to calculate SSA (m²/cc).
 - Used to calculate Blaine (m²/kg).
- Results parameters:
 - Changes the values used in the %<, %> and % between graphs.
- Graphs:
 - Sets which graphs are plotted.
 - Sets which results are output to the records table.
- X-axis:
 - Changes the x-axis duration shown on the trend graphs.

- Y-Scaling:
 - Gives options for how the automatic Y-axis scaling operates. This can be overridden.
- Average:
 - Allows the time period to use when averaging mode is enabled on graphs.
- Print parameters:
 - Allows the text at the top of print-outs to be set.
 - Allows the logo at the top of print-outs to be set.
- System ID:
 - Allows an ID to be set which appears in the application title bar. Generally used when multiple sizers are running on one PC.

For more in-depth explanations of each parameter function please refer Software Manual.

7.4.2 Identifying status of alignment

After the parameters page has been set up the operator must check the alignment of the system.

This section assumes the sample cell is clean, the process of cleaning a sample cell is explained in the section 'Routine Maintenance'.

To check the alignment on the system, click the "Check Alignment" button in the software.



Figure 133 - Menu items.

Check alignment button.

The Xoptix series of particle sizers are advanced laser diffraction instruments. As such, correct optical alignment is key to ensure successful operation of the equipment.

The system is designed to stay in alignment under most conditions, however, under certain circumstances the alignment may shift out of position. Such circumstances include:

- Excessive vibration.
- Stress or unusual loading on the optical assembly.
- Arbitrary adjustment by untrained personnel.

It is therefore important to be able to recognise good alignment and bad alignment.

To help identify good and bad alignment an explanation of what is happening within the system is shown below.

7.4.2.1 Correct Alignment (Optical)

In this case all the light from the laser beam passes through the main detector and images full on the alignment detector. Small movements of the laser due to vibration etc. will not change the scattering on the main detector.

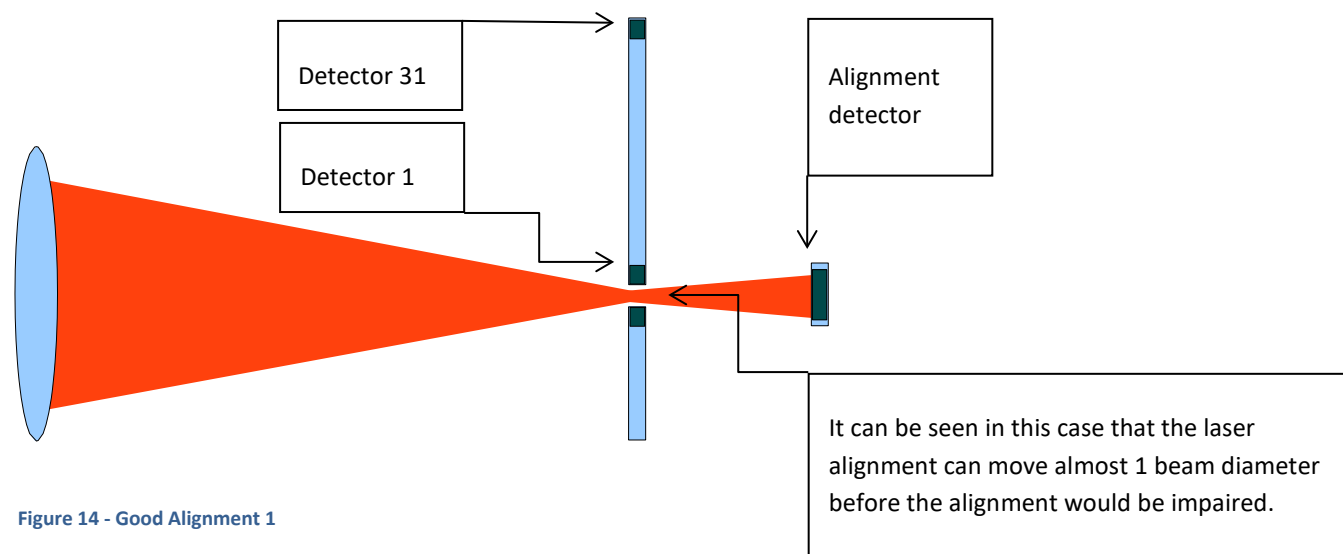


Figure 14 - Good Alignment 1

Correct Alignment (Software)

To see how the light is scattering on the detector within the software the operator must click on the "Check Alignment" button in the software; this brings up the "Live Data" page displaying the light scattering values in the alignment table and graph.

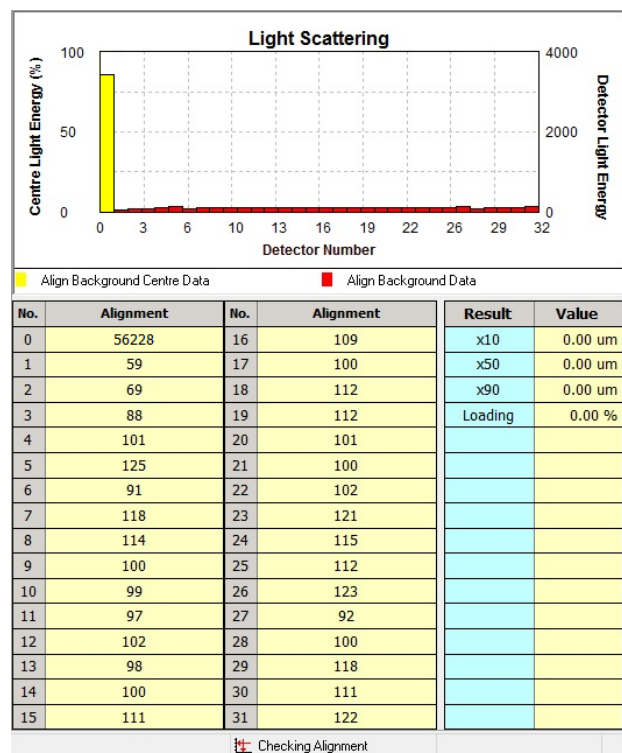


Figure 15 - Good alignment 2

The key points in figure 15 are:

- The yellow bar should be greater than 60%.
- Detector 1 and 2 should be at minimum values possibly while being at a similar level.

7.4.2.2 Incorrect Alignment (Optical)

In this case the light from the laser is sufficiently aligned so that it passes through the hole, however as it is not passing centrally through the main detector, very small vibrations can move the laser to scatter on the first detectors. This can make the instrument think that real particles are present.

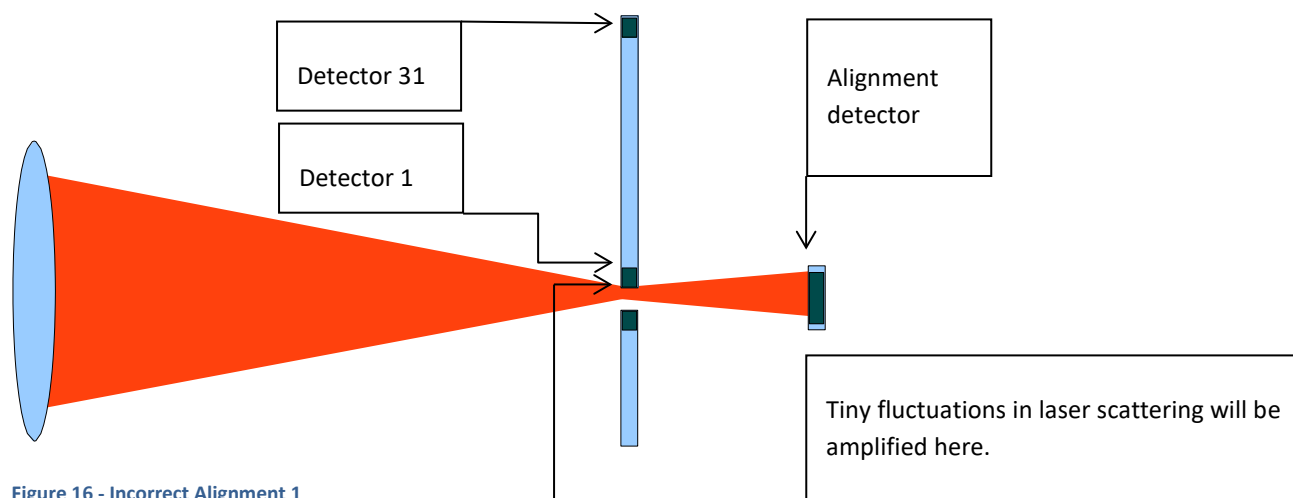
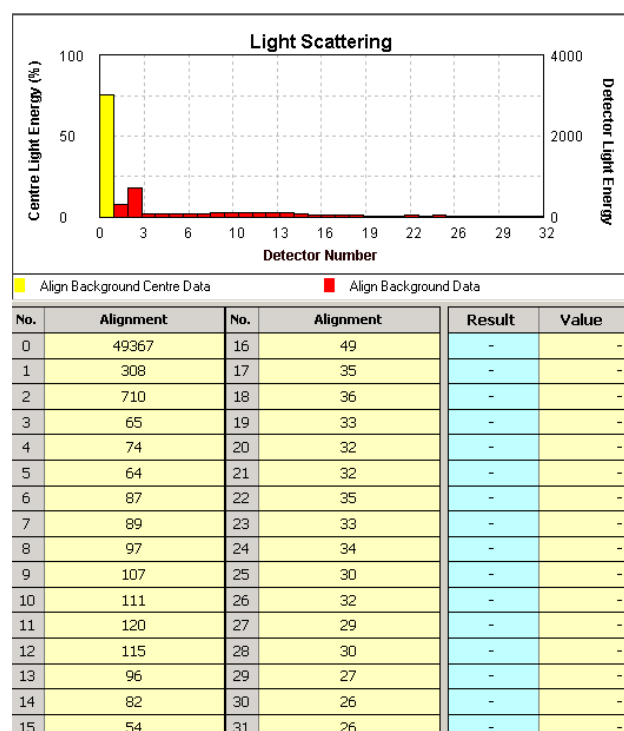


Figure 16 - Incorrect Alignment 1

7.4.2.3 Incorrect Alignment (Software)

Within the software on the “Check Alignment” tab incorrect alignment appears as follows:

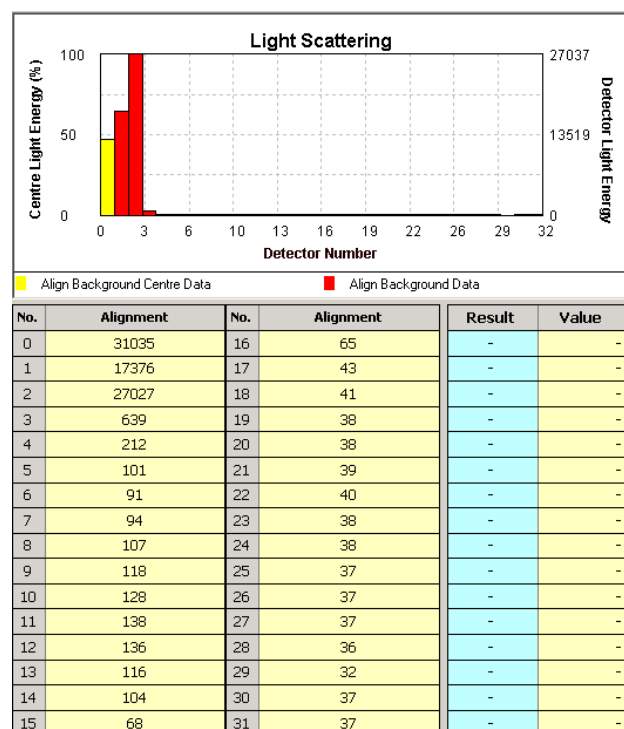


The key points in figure 17 are:

- a) Channel 1 and 2 are high.
- b) Channel 1 and 2 are at dissimilar values.

Figure 17 - Incorrect alignment 2

In an extreme case incorrect alignment may appear as:



The key points in figure 18 are:

- a) Channel 1 and 2 are high.
- b) Channel 1 and 2 are dissimilar values.
- c) Channel 0 is low (below 50).

Figure 16 - Incorrect alignment 3

General figures for detector channels 1 and 2 that point to incorrect alignment on a new system are as follows (varies per system). On systems that have been used for some time these may increase

	XO220P / XI220P	XO550P / XI550P	XO1100P / XI1100P
1	>250	>350	>500
2	>250	>350	>500

7.4.2.4 Complete misalignment (Optical)

Complete misalignment is when none of the laser is getting through the main detector. The following picture is a representation of how a complete misalignment may appear within the system:

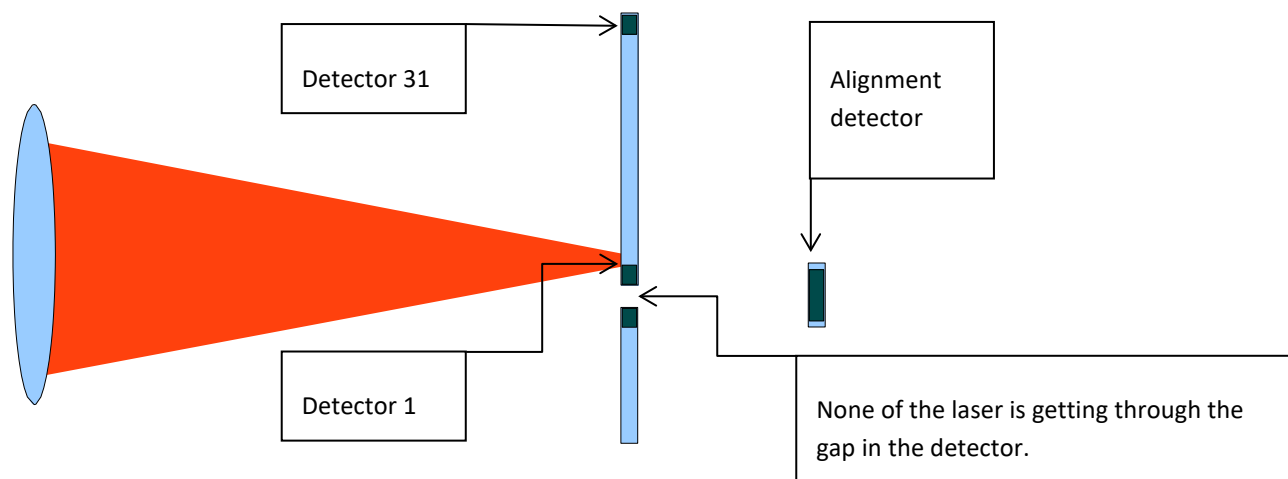
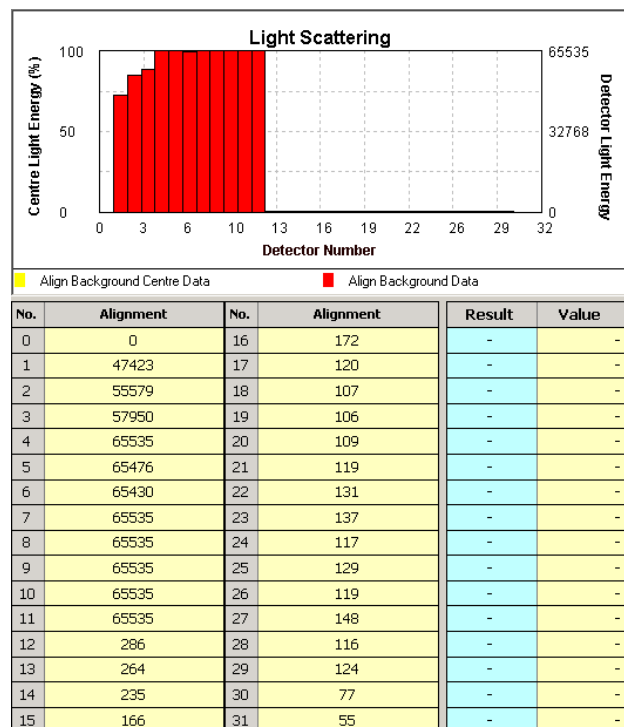


Figure 19 - Complete misalignment 1

7.4.2.5 Complete misalignment (Software)

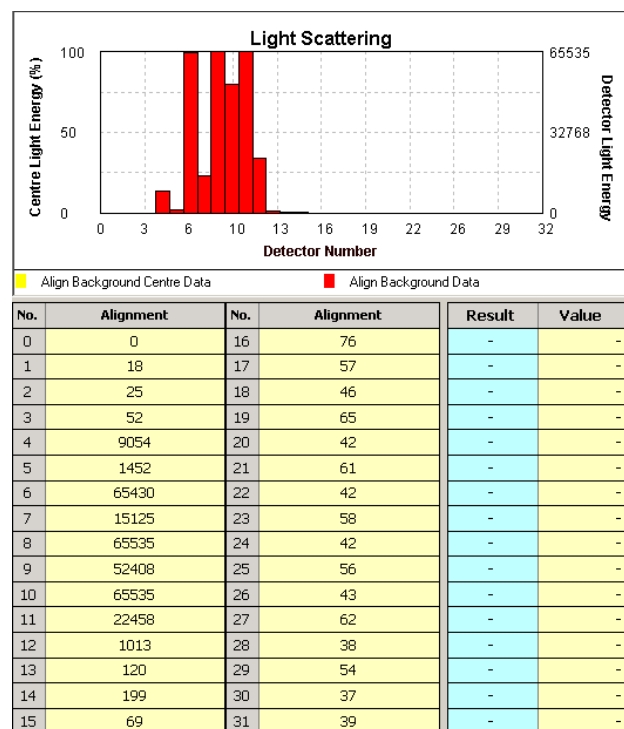
Within the software a complete misalignment can appear in many stages, the critical attribute is that there is no yellow bar appearing from channel 0. Below are some examples of complete misalignment.



The key points in figure 20 are as follows:

- There is no data in channel 0.
- Channels between 0-11 are saturating (reaching values of 65535).
- Channels next to each other are saturating.

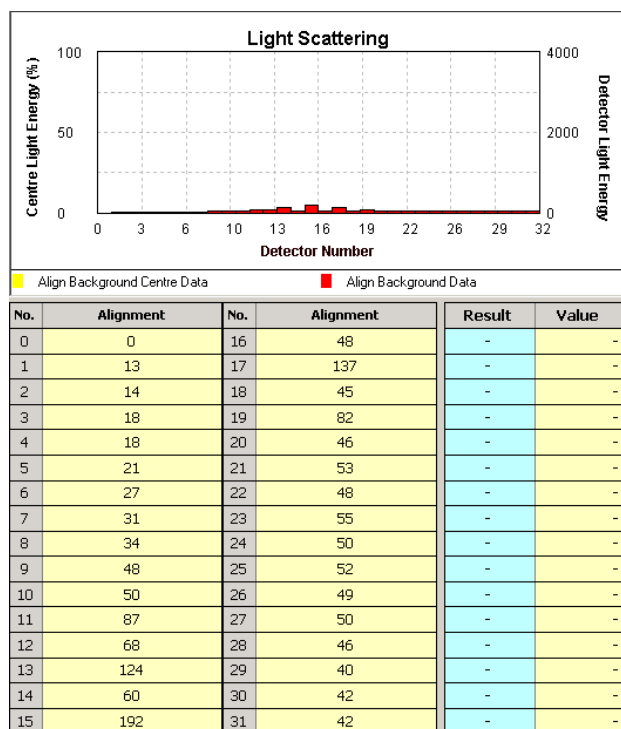
Figure 20 - Close complete misalignment



The key points in figure 21 are as follows:

- There is no data in channel 0.
- There is data between channels 0-12 but they are not all constantly saturating as in figure 19.

Figure 17 - Medium complete misalignment



The key points in figure 22 are:

- There is no data in channel 0.
- There is no significant data between channels 0-12.

Note: Occasionally in this scenario there can be one single saturated channel after channel 12.

Figure 18 - Absolute complete misalignment

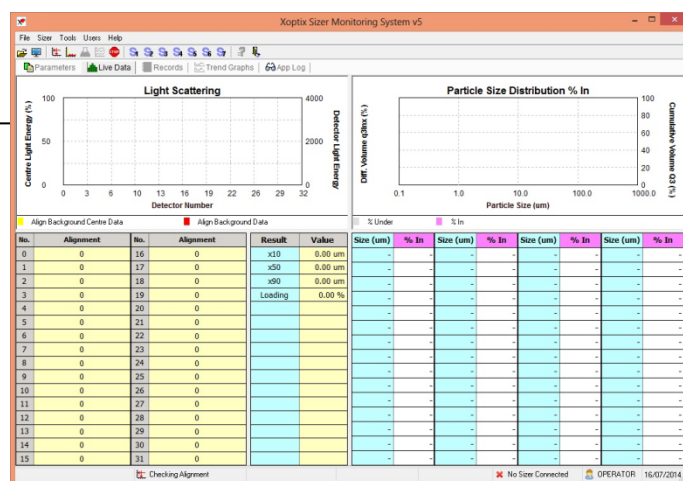
In all the above cases re-aligning the system is possible.

7.4.2.6 No data (Software)

If the “Check Alignment” screen is showing absolutely no values (see fig 23) while the sizer is switched on and connected to the computer check the following:

- Check the COM port status on the status bar in the software has a green tick next to it.
- Check the sizer is fully connected.
- Check the sizer is receiving power.
- Click the “Check Alignment” button in the software again and wait 10 seconds.
- Check the sizer display (not present in PharmaSizer and ATEX/UKEX systems) to see if it displays “Laser ON”.

Check alignment button.



COM port status.

Figure 19 - No values.



Figure 20 - Sizer LCD.

If none of the above actions improve the situation call your service representative.

7.4.3 Setting the alignment

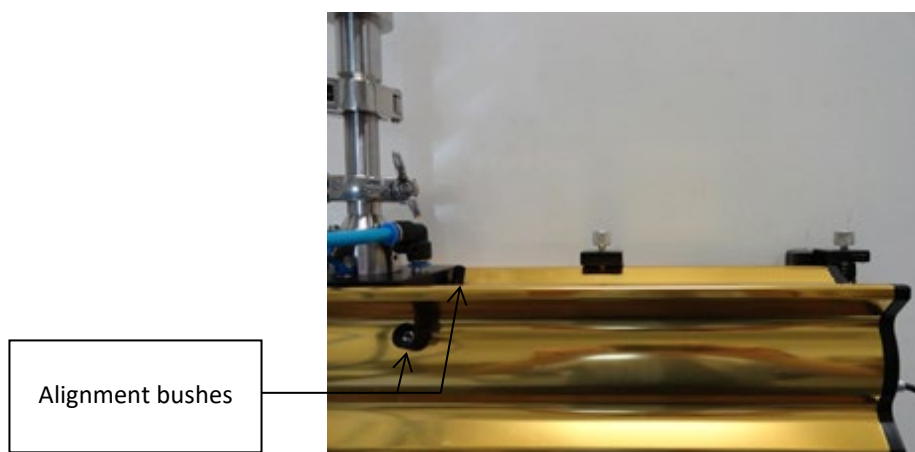
The process of aligning the system requires the following:

- Access to the Xoptix sizer (fully connected and powered).
- A computer or a control unit model XOSC36/XOSC46 or later connected to the sizer within view.
- An alignment tool.



Figure 21 - Alignment tool.

Alignment is carried out by adjusting the alignment bush X and Y adjusters located on the sizer body shown below in figure X. Models may vary.



Two alignment scenarios will be explained below:

- i. Small alignment adjustment – used for “Incorrect misalignment” in section ‘Small alignment adjustment’.
- ii. Intensive alignment adjustment – used for “Complete misalignment” in section ‘Intensive alignment adjustment’.

7.4.3.1 Small alignment adjustment

While checking the alignment display on the computer or control unit display (in alignment mode) constantly:

1. Adjust one Alignment bush a very small amount (typically less than $1/10^{\text{th}}$ of a turn at a time).
2. Watch the reaction of the alignment screen.
3. Adjust the alignment in the one bush steering towards “Correct alignment” shown in section ‘Identifying status of alignment’.
4. Once the one alignment bush has only a small improvement, no effect or makes the alignment worse, change to aligning the other alignment bush.
5. Carry on aligning the two alignment bushes iteratively until the inner two channels are at similar low values, and detector 0 is at maximum.

The above steps become a lot quicker to carry out once the user has gained practice typically, a small alignment adjustment takes less than a minute.

7.4.3.2 Intensive alignment adjustment

A slightly different procedure is required when the system is completely misaligned. Again, while checking the alignment display on the computer or control unit display (in alignment mode) constantly:

1. Steer the light to the left-hand side of the graph using both alignment adjusters – if nothing happens within quarter of a turn on one adjuster; turn it back to the original position and attempt with the other adjuster.
2. Carry on using the alignment tool until there is a light value present in channel 0.
3. Adjust one alignment adjuster until the channel 0 is at its maximum point.
4. Adjust the second alignment adjuster until channel 0 is at its maximum point.
5. Carry out the instructions from “Small alignment adjustment” steps above.

It is important to remember that unless anybody has moved the alignment significantly, the correct alignment is likely to be within less than half of a turn of the current positioned adjusters so adjustment should be very slight.

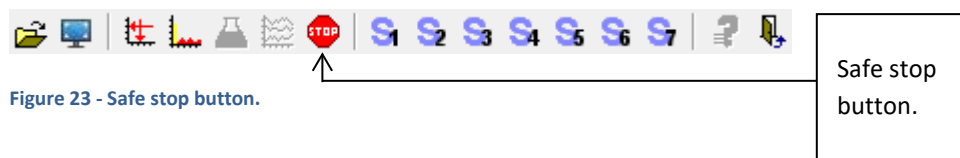
Intensive alignment can take a few minutes but it is very unusual for the system to be misaligned by such an amount.

7.4.4 Setting up sequences

SAFETY WARNING – Ensure any connected valves or digital inputs are safe to toggle before using the sequences.

Having the knowledge to set up sequences is required before carrying out a measurement as the “Safe Stop” button has a default sequence assigned which should be configured for the operator’s requirements.

In this section it will be explained how to assign a sequence to the “Safe Stop” button, this knowledge can then be applied to assign sequences to other buttons in the software.



The safe stop button is the button used to stop any measurement for any reason, be it an emergency stop or just stopping the system carrying out a manual measurement.

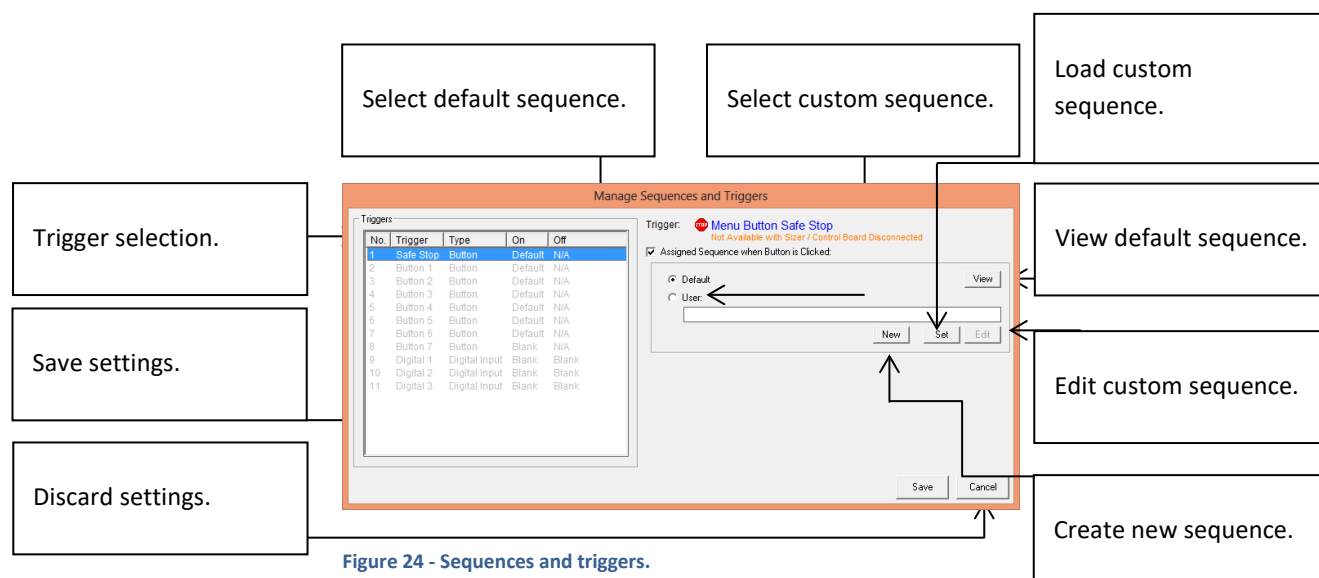
The default safe stop sequence carries out the following functions:

1. Close valve 1.
2. Close valve 2.
3. Close valve 3.
4. Close valve 4.
5. Close valve 5.
6. Close valve 6.

The operator must know what state they wish their connected valves to be in during a stop. Writing down the desired order and state of each valve helps when it comes to creating a sequence.

Sequences are used for automating processes within the Xoptix software. The section in the software for creating and assigning sequences is accessed by first clicking “Tools” in the menu bar, and selecting “Sequences and Triggers”.

A new window will have popped up as shown below.



7.4.4.1 Checking Sequences

On the left-hand side of the window it displays whether a default or user customised sequence is assigned to each sequence enabled button or digital input.

To view a previously assigned sequence the user must check whether it is using a file or whether it is using a default sequence. Click on the sequence in the left-hand side of the window. If the sequence is using a default setup then this can be checked by clicking the “View” button on the right-hand side of the window. If the sequence being used is from a file then this can be checked by clicking the “Edit” button on the right-hand side of the screen.

7.4.4.2 Plan the Sequence

Before trying to write a sequence establish what each valve number controls and the desired outcome of the sequence.

For example, a sequence for a general measurement may be planned like this:

“I have the following valves connected and these are their functions:

- Valve 1 - Controls the main system air.
- Valve 2 - Controls the cell clean.
- Valve 3 - Controls the sample air.

From this information, I want to write a sequence to carry out the following actions in this order:

1. Switch on main system air.
2. Wait a few seconds for the flow to stabilise and any residual dust to clear.
3. Make a background measurement.
4. Switch on the sample valve.
5. Measure the sample for one hour.
6. Stop the measurement.
7. Close the sample air valve.
8. Wait a few seconds.
9. Switch off the main air supply.

From here it is then possible to replace the descriptions and valve names with the valve numbers:

1. Open Valve 1.
2. Wait 10 seconds.
3. Measure background.
4. Open valve 3.
5. Measure sample 60 times (on a 60 second measurement set on parameters page).
6. Stop the measurement.
7. Close valve 3.
8. Wait 10 seconds.
9. Close valve 1.

This list can then be used in the section ‘Creating Sequences’.

7.4.4.3 Creating Sequences

To begin creating a sequence simply select the button you wish to configure (in this case the “Safe Stop” trigger), and click the “New” button on the right-hand side of the window.

A new window will appear with a list on the left-hand side and a table on the right side. The table on the right-hand side is what is carried out by the sequence when it is executed, starting from the action at the top, moving down sequentially until it reaches the bottom. A single shot sequence will only be carried out once while a continuous sequence will loop back up to the top of the list after it has reached the end.

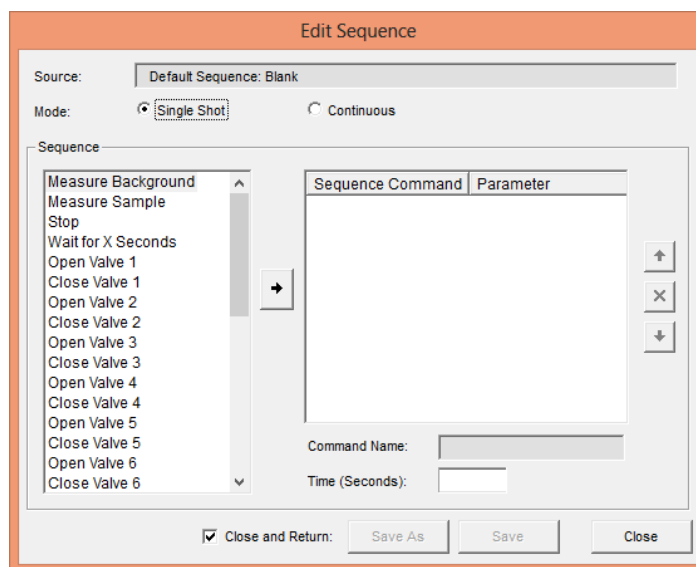


Figure 25 - Create new sequence.

By highlighting an option on the left-hand side and clicking the arrow between the list and the table the action is carried over into the sequence. If a mistake has been made moving an action over, it can be removed from the sequence by highlighting the action and clicking the “X” button to the right-hand side. Alternatively, if an action has been placed in the wrong position, this can be adjusted with the up and down arrows positioned to the right of the sequence actions.

By using the list, the operator made of the desired state of valves for a safe stop, a sequence can now be made.

Once the sequence has been made click the “Save As” button at the bottom of this window, assigning it a relevant name and saving it in a location. Once the file has been saved, this window will close and the new sequence will now be assigned to the “Safe Stop” trigger.

USER WARNING – The “Stop” function within the sequence creator does not carry out the safe stop sequence, it is just a command to stop the sizer from measuring.

Note: In the XOSC3x and XOSC4x control units, valve 2 is connected to the cell clean and valve 1 is connected to the sample/probe air.

7.4.4.3.1 Cell clean sequence example

The cell clean feature is simply a blast of air to clean the cell windows; the sequence is as follows (where valve 2 is the valve for the cell clean):

1. Open Valve 2.
2. Wait 1 second.
3. Close Valve 2.

This sequence opens the cell clean valve, blasts air over the cell window for one second, then stops.

The cell clean sequence should be carried out while the purge and sheath air are both on, but the sample air is off (no sample being drawn through).

7.4.4.4 Assigning a previously created sequence

If a different sequence has already been created and the user would like to use that, highlight the trigger to change, click the “User:” radial button on the right-hand side and click the “Set” button. Navigate to the previously saved sequence and click “Open”; this will assign the sequence to the trigger.

Once everything is done click the “Save” button at the bottom of the window.

By clicking the “Safe Stop” button, or any other sequence button assigned a sequence, the sequence will now be run.


7.4.5 Carrying out a manual measurement

Once the system is fully aligned and the parameters page has been set up the operator has the choice of two different methods of carrying out a measurement.

1. Manual measurement.
2. Automated measurement.

This section details how to carry out a manual measurement. A manual measurement is where the operator is present for each action carried out by the system.

Having ensured all the connections are secured (pneumatic and electrical) the following actions may be taken to gather a measurement:

1. Switch on the air supply (do not switch on the sample valve).
2. Check the air levels on the XOSC3X are correct.
3. Take a background measurement by pressing the measure background button ().
4. Wait for the measurement to be carried out – a progress bar is shown on the status bar at the bottom of the software (v5 and above).
5. During the background measurement, the data bars will turn a lighter shade of red, reverting to the standard red when the measurement is complete (see figures 30 & 31). The cells below the graphs will turn green upon a successful background.

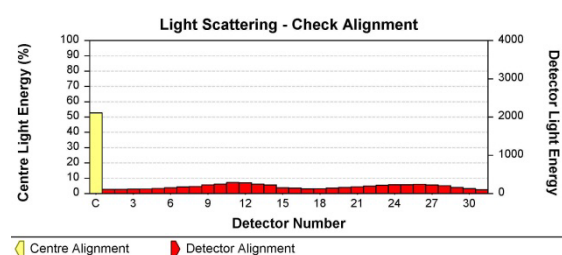


Figure 26 - Red bars before and after background.

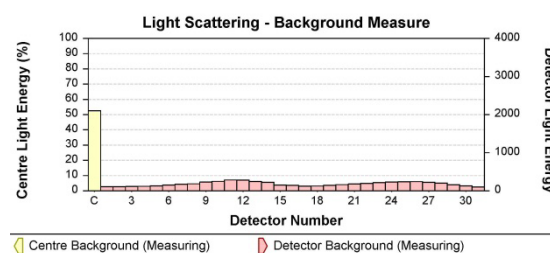




Figure 27 – Light red bars during background measurement.

6. Click the check sample button ().
7. Switch on the sample valve (default valve 1) to start taking sample from the process. It may be necessary to adjust the sample air on the XOSC3X to optimise the sample flow, to ensure that the sample loading is within limits specified on the parameters page.
8. Click the start measure button ().

The measurement is now being carried out, to stop the measurement simply press the "Safe Stop" button.

Occasionally the sample cell windows can become dirty or abraded dependant on how the system is being used.

If the cell clean function (see section 'Cell clean sequence example') does not clean up the background then it is likely the cell windows will need either cleaning or replacing.

The following sections detail how to clean and replace the cell windows in the different Xoptix products.

The following tools are required for each system:

- 1x 3mm Allen Key.
- Isopropyl alcohol.
- Good quality lens cleaning tissue.
- Tools where necessary to remove pipes from the sample cell.

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

SAFETY WARNING – Before carrying out maintenance ensure the sizer is switched off and no sequences are running.

8.1 Standard dry system

SAFETY WARNING - Please ensure before connecting or disconnecting any air fittings or any disassembly of the system is carried out that the air supply to the system is switched off and under no pressure.

SAFETY WARNING – Before carrying out maintenance ensure the sizer is switched off and no sequences are running.

8.1.1 Cell Strip Down

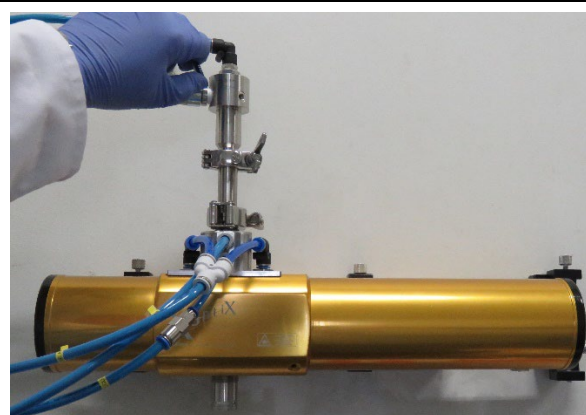
This section describes the removal and complete strip down of the Xoptix pharmaceutical dry flow cell. The following sequence is aimed to give a basic overview of a cell strip down but this is not the only possible procedure. For example, in the following sequence, the cell is removed complete with the eductor, sample hose tail and dry flow cell nozzle still attached to the cell. It may be preferred to remove these components before removing the cell (please refer to your company's standard operating procedure).

8.1.1.1 Dry flow cell removal

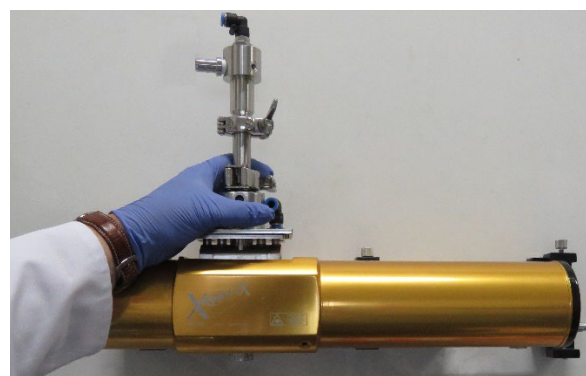
1. To remove the flow cell, remove the outlet hose and unscrew the cell retaining screw located underneath the sizer. This may be tight due to the sealing O-ring around the cell outlet.



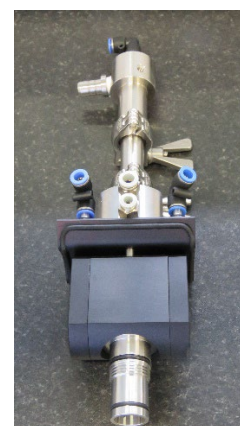
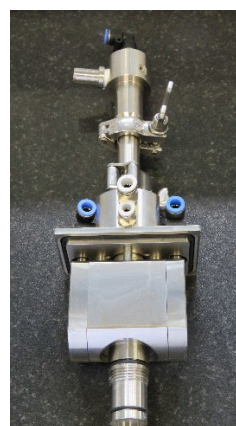
2. Remove the sample hose and all the pneumatic pipes (shown in blue).



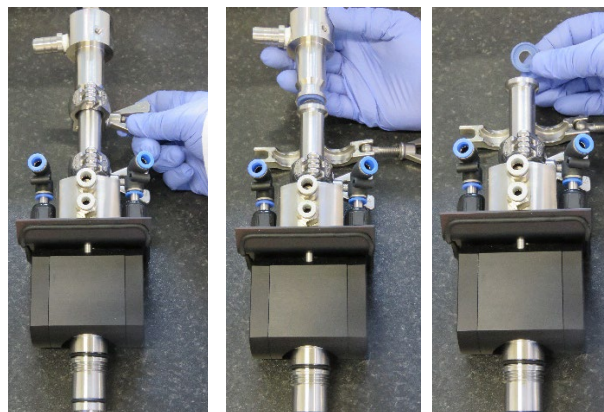
3. Remove the flow cell vertically from the cavity. This may be tight due to the sealing O-ring around the cell outlet.



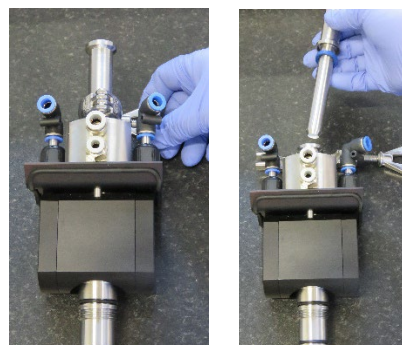
4. Removed dry flow cell. IntelliSizer (left), and standard system (right)



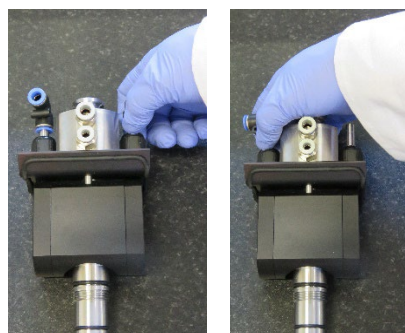
5. Remove the eductor by removing the tri-clamp and lifting the eductor off. Remove the tri-clamp seal.



6. Remove the dry flow cell nozzle by removing the tri-clamp and pulling the nozzle up out of the flow conditioning module. Remove the tri-clamp seal.






7. If not already removed, remove the two pneumatic elbow connectors from the cells purge pipes.



8. Loosen the two purge pipe glands.



<p>9. To remove the cell ends to allow for cleaning or changing the dry flow cell windows undo the four M4 captive screws using a 3mm Allen key.</p>	
<p>10. Ensuring that all the screws are free (loose from the middle section of the cell) slide the cell downwards and remove completely.</p>	
<p>11. Cell end Y removed. Note the pin and groove to ensure that the cell end will only fit on the correct side of the cell.</p>	
<p>12. Repeat steps 8 to 11 for the remaining cell end (cell end X).</p>	

8.1.1.2 Dry flow cell refitting

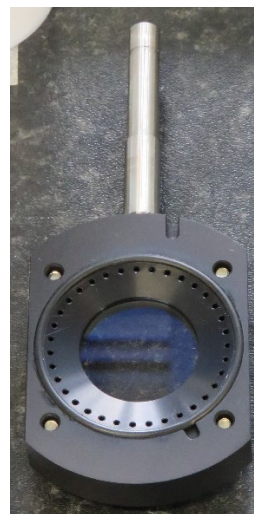
To refit the dry flow cell simply follow section 8.1.1.1 in reverse (step 12 to 1).

Note: When fitting the cell end X and Y back onto the cell, ensure the correct one is fitted by lining up the pin with the groove on cell end X.

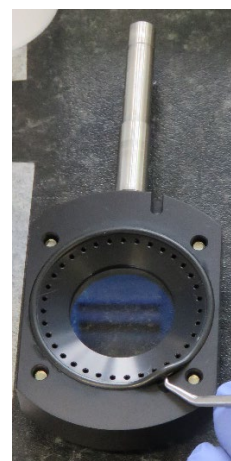
8.1.1.3 Dry flow cell window removal

This section details the removal of the window (glass) from the cell ends. The instructions take place after step 9 from section 8.1.1.1

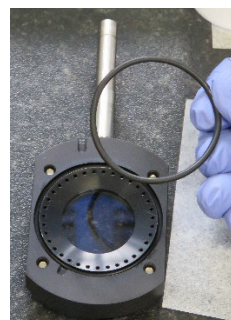
1. Check the cell window retaining ring O-ring for signs of wear and if required replace it by following the sequence below.



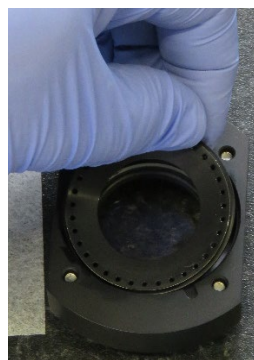
2. Using a screwdriver or O-ring removal tool lift the O-ring up using the small recess for access.




3. Remove the cell retaining ring O-ring.



4. Remove the cell window retaining ring.



<p>5. Remove the cell window. Check the window for scratches and any other damage. If the window shows little sign of wear then clean and place the window back within the cell end, otherwise replace the window the a new one. The cell windows are coated on one side. The coated side is marked with arrows on the edge of the window pointing towards the coating. The coating should be placed against the O-ring, so on the outside of the cell when the cell is reassembled.</p>	
<p>6. To clean the window, take a sheet of lens cleaning tissue and gather the four corners to form a bulb shape. Apply 1-3 drops of pure ethyl alcohol or isopropyl alcohol to the paper and wipe the window with a single sweeping action. Discard the lens cleaning paper and repeat until the window is clean.</p>	
<p>7. Repeat steps 1 to 6 for the other cell end.</p>	

8.1.1.4 Dry flow cell window refitting

Simply follow the above section in reverse (step 5 to 1).

8.2 Standard wet system

SAFETY WARNING – Please ensure before commencing the work that all utilities to the cell (water, dispersants, compressed air, electricity etc.) are all isolated.

SAFETY WARNING – Before carrying out maintenance ensure the sizer is switched off and no sequences are running.

8.2.1 Cleaning the flow cell windows

Note: The outer facing part of the cell window can be cleaned without taking the cell apart – if only the outside of the cell windows require cleaning carry out steps 12 to 15 for both windows.

Below are the steps required to completely clean the cell windows (both inner and outer surfaces).

1. Disconnect all the sizer cable from the sizer.
2. Drain the cell contents.
3. Disconnect the wet cell sample hose.
4. Release the sizer from the anti-vibration mounts and clean off all dust before taking the sizer to a clean dust free area.
5. Remove the wet flow cell retaining screw.
6. Remove the wet flow cell keeping the system vertical, taking care not to drip any liquid inside the sizer cavity.
7. While holding the cell to avoid touching the windows, unscrew the 4 screws from the cell (2 screws on either side), these screws are captive and only need to be unscrewed until they fall loose.
8. Over a soft surface (ideally foam or rubber) keep the 2 cell pieces horizontal in your hand and grip the top half of the cell and the cell spacer together. Lift these away from the bottom half ensuring the bottom cell window has not stuck to the bottom of the spacer.
9. Place the bottom half of the cell on the soft surface.
10. Turn over the top half of the cell until it is face up in your hand.
11. Carefully lift off the cell centre spacer ensuring the cell window is not sticking to the bottom of the spacer.
12. Remove one cell window by using a clean piece of optical tissue paper and gently pressing from the outside.
13. Take a sheet of optical cleaning paper and gather together the four corners to form a bulb shape.

14. Apply a small amount (1-3 drops) of isopropyl alcohol to the bulb end of the paper.
15. Wipe the window with a single sweeping action, discarding the paper afterward.
16. Repeat steps 13 to 15 cleaning both sides of both of the windows until they are clean.
17. Place the windows into the cell ends ensuring if there is an arrow on the side that it is pointing outward.
18. Repeat steps 12 to 16 for the other cell window.
19. Reassemble the cell ensuring the cell spacer is the correct orientation.
20. **IMPORTANT:** When the cell has been reassembled, **BEFORE** putting the cell in the sizer, connect it to the sampling system and run it for several minutes to check for any leaks. A leaking cell can potentially cause damage to the interior of the sizer while also interfering with measurements.

8.2.2 Replacing the flow cell windows

1. Carry out steps 1 to 12 from section 'Cleaning the flow cell windows'.
2. Remove the cell window from the other cell end using a clean piece of optical tissue paper.
3. Place the new windows into the cell ends ensuring if there is an arrow on the side that it is pointing outwards.
4. Re-assemble the cell in the reverse order it was taken apart.
IMPORTANT: When the cell has been reassembled, **BEFORE** putting the cell in the sizer, connect it to the sampling system and run it for several minutes to check for any leaks. A leaking cell can potentially cause damage to the interior of the sizer while also interfering with measurements.

9.1 Introduction

9.1.1 General Overview

It is essential that any monitoring equipment is capable of being verified in terms of it performing within its specifications. For laser diffraction instruments, this is normally done using standard traceable particles.

However, the fact that Xoptix systems are frequently installed in processes, where the introduction of 'foreign' matter into the process causes issues, traceable standards such as glass beads, or latices are impractical. For this reason, the reticle was introduced.

The reticle is a mechanical system, which comprises a precise way of introducing a traceable distribution of particles printed onto a piece of glass into the measurement region, ensuring accurate, repeatable and reproducible measurement.



Xoptix Reticle

9.1.2 System Compatibility

The Xoptix reticle is compatible with all Xoptix Dry Sizers which have the Flow Conditioning Module (FCM) shown below:



Compatible FCM.

If your system has the older style of FCM, shown below, then you will need a modified FCM with a hole diameter of 16.7mm to accommodate the reticle.

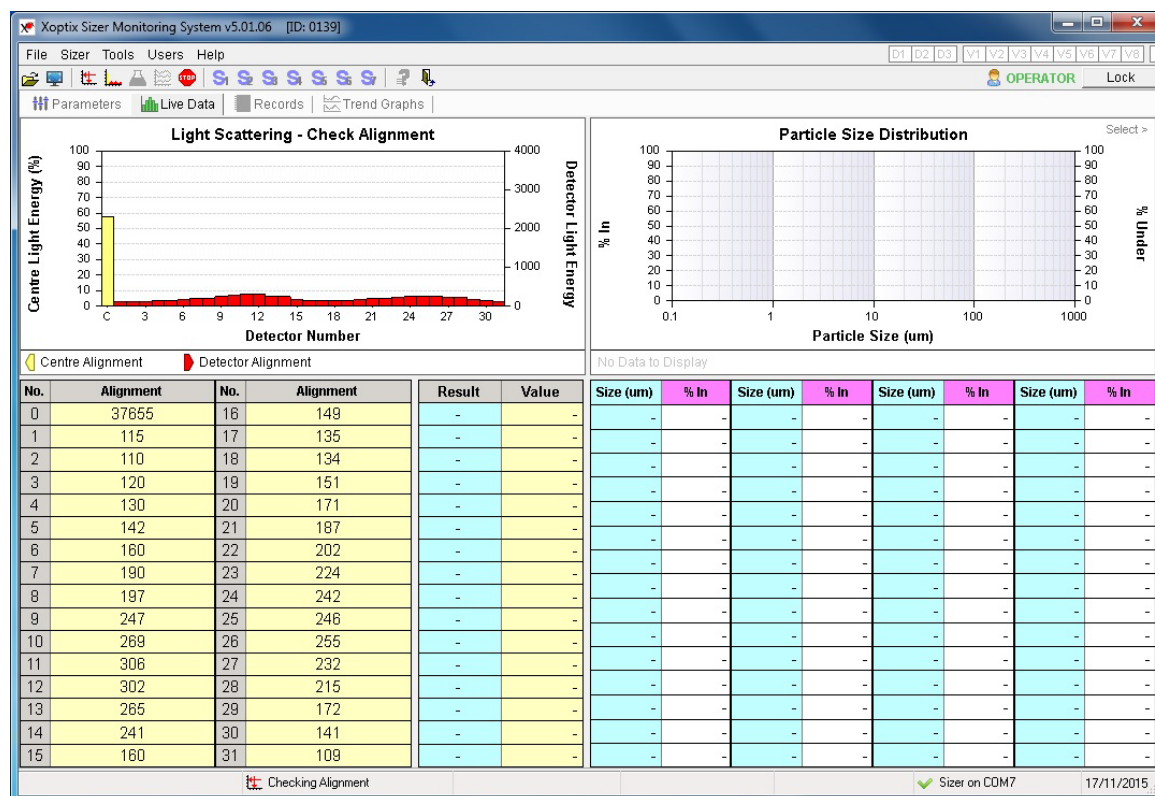


Non compatible FCM.

9.2 Procedure

9.2.1 Check that the instrument is installed correctly.

9.2.2 Check that system is aligned the windows are sufficiently clean to make a measurement. A typical alignment is shown below. The important points are that detectors 1 and 2 are of a similar level to 4-10, and that no detector is significantly lower or higher than its surrounding detectors. All detectors on a clean system should be <1000, although, it may be possible in principle to measure with background values higher than this.



If the background is high, try an automated cell clean to try and improve this. If the background is improved, but not perfect, repeat the automated cell clean, until there is no improvement.

If the background is still too high, remove the sample cell, and check for dirt or scratches on the cell windows. If dirty, perform a manual clean. If the windows are scratched report this or replace the windows.

9.2.3 Make a background measurement, and record the levels of Detector 1, Detector 2, maximum detector number (and value), % difference between detectors 1 and 4, and Laser power on the System Performance certificate.

9.2.4 Turn off the air to the instrument. This can be done by switching an automatic valve (where fitted) to isolate all air to the control box, but if a manual valve is available, it is recommended that this is also switched off.

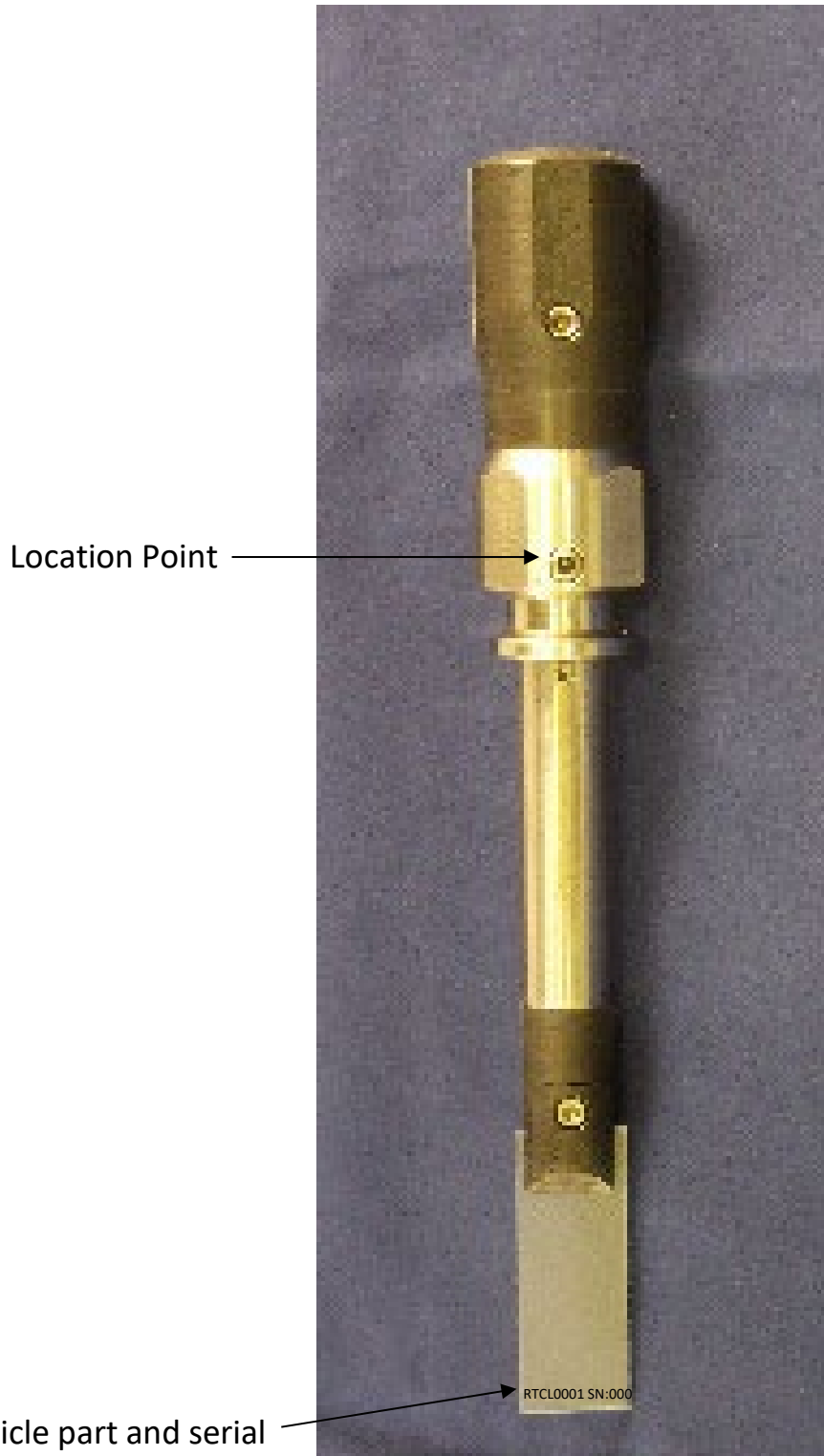
9.2.5 Remove Venturi eductor and sample nozzle by removing their tri-clamps, and taking them off the sizer. If the automated cell clean did not sufficiently clean the cell windows, it may be necessary to remove the sample cell and manually clean or replace the windows.

9.2.6 Remove the reticle cover by removing the tri clamp on the reticle assembly.

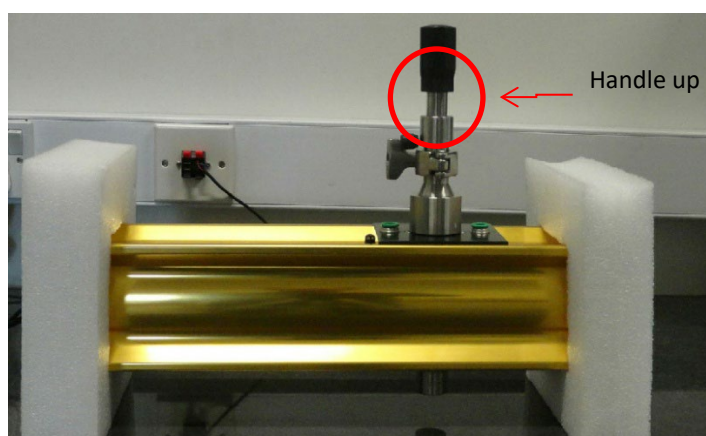
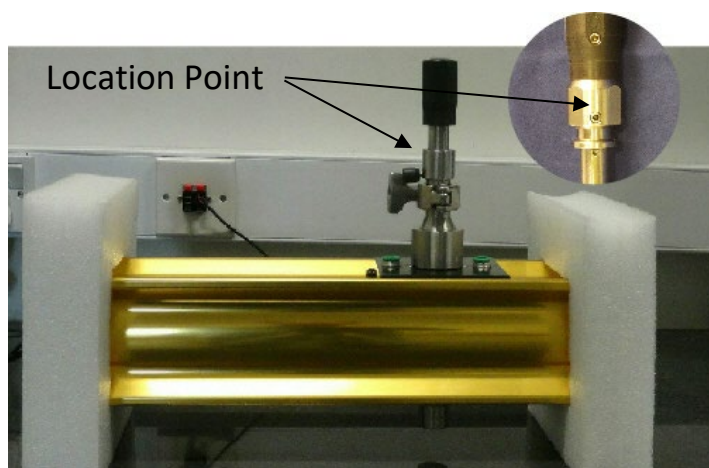
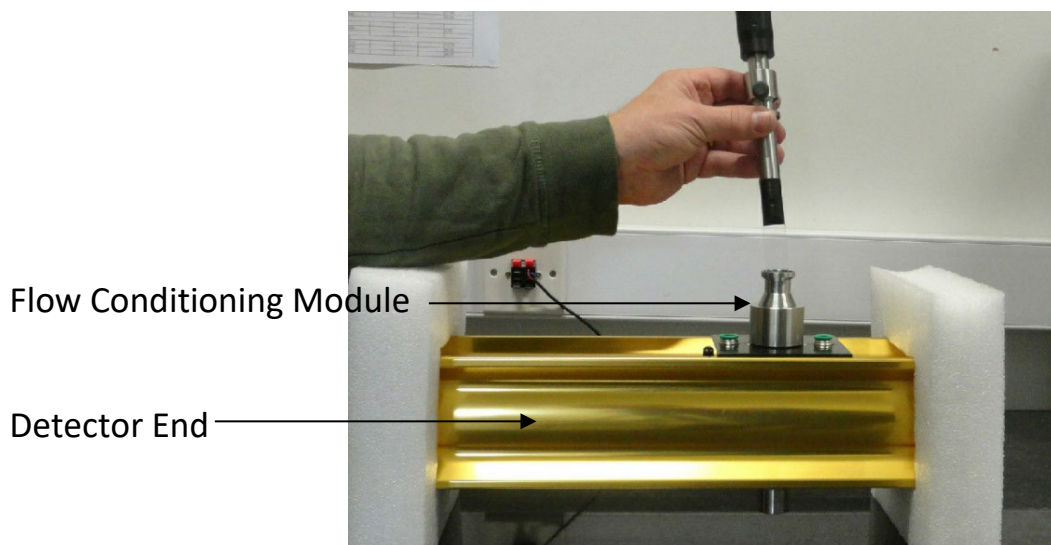
9.2.7 Check that the reticle is clean and free from chips and scratches. Only clean the reticle glass if absolutely necessary using lint free tissues and ethanol or IPA. If the reticle does have chips or

scratches then check that these were recorded on the previous Reticle Certificate. If the damage is not shown on the Reticle Certificate then the reticle should be returned to Xoptix for re-certification.

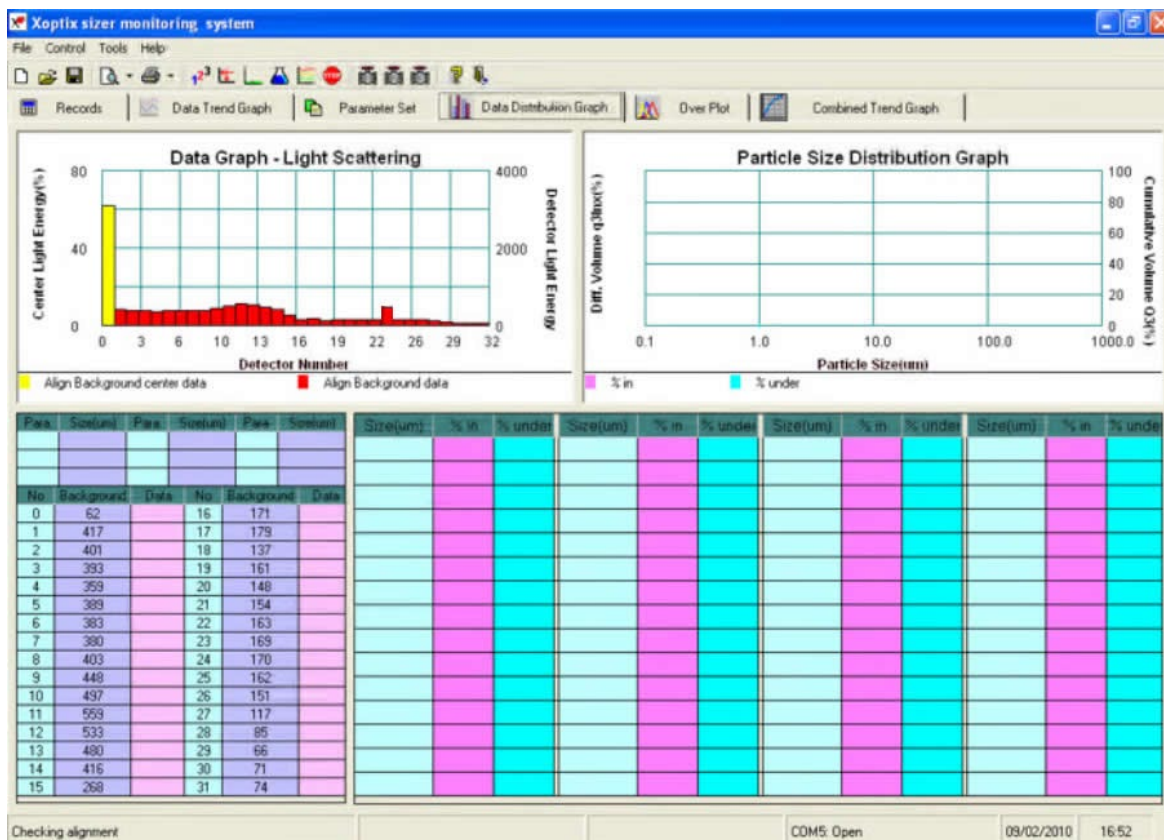
- 9.2.8 Ensure that the dots on the reticle glass are correctly orientated in the reticle holder. The RTCL0001 and the serial number should be at the bottom of the glass slide and the writing, and hence the dots, should be readable and not mirror image when the location point is facing you.



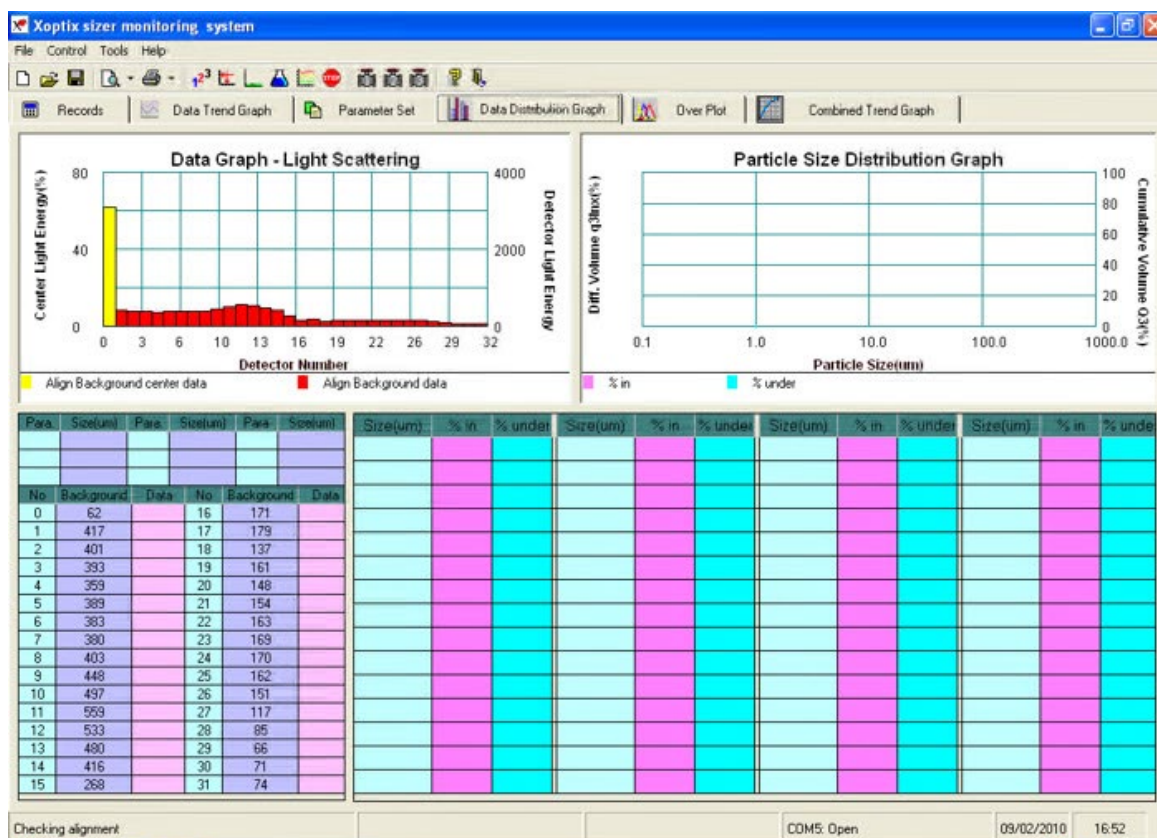
- 9.2.9 Insert the Reticle into the flow conditioning module, ensuring that the dots and serial number are towards the detector end (longer section), with the reticle in the background position, handle up.



- 9.2.10 Check the alignment of the system, it may be necessary to adjust this slightly when the reticle is used.
- 9.2.11 If you see a high channel then turn the reticle very slightly until the high channel (reflection) is removed (see below).



Example of a reflection.



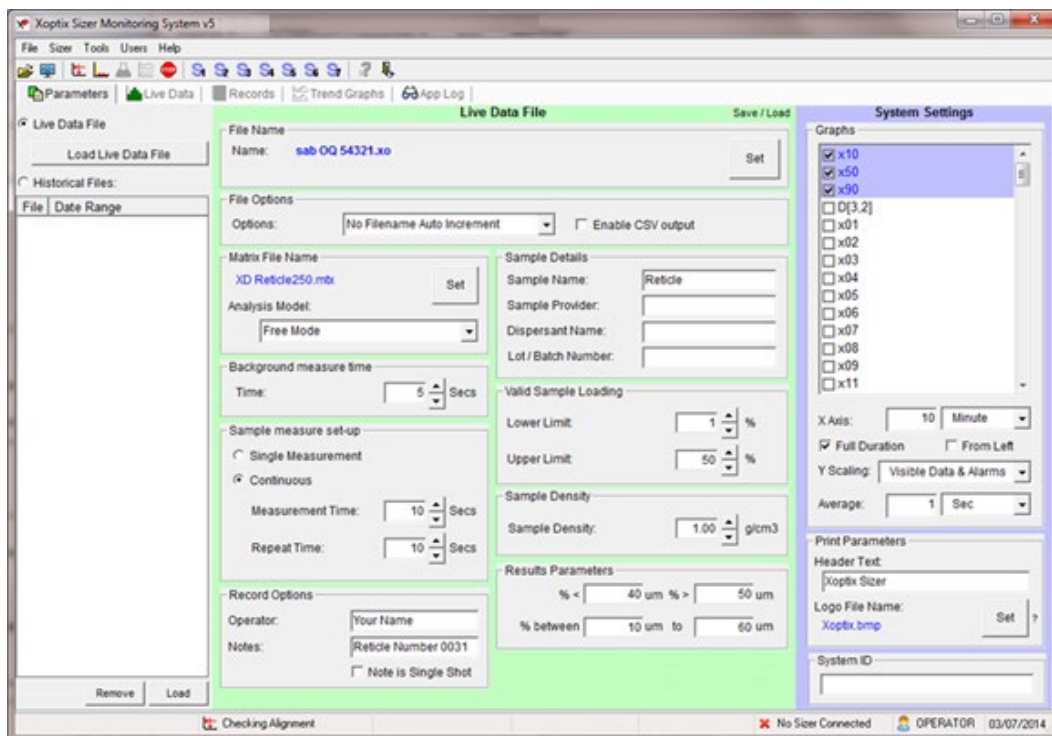
No reflection.

9.2.12 Ensure that the reticle is perpendicular to the laser, and make a background measurement (5 seconds or greater).

9.2.13 Enter 'Check sample scattering' mode, and push the reticle down to the sample position, and make a measurement with the following settings measurement time 10 seconds, continuous, Sample

concentration limits low 1% high 50%, Free mode, Matrix Reticle, watched parameters x10, x50, x90 and sample loading, Trend window 10 minutes.

These settings are shown below:



Create a new file name and measure the reticle for at least 5 minutes.

- 9.2.14 Print out the records page and the trend graph, and the average result from the entire 'window of measurement', and use these to complete the System Performance Certificate. Attach these to the System Performance Certificate, sign the certificate and the OQ document, and where relevant, obtain a counter signature for the documents.
- 9.2.15 Remove the reticle, inspect and clean if necessary, and store carefully.
- 9.2.16 Check the alignment of the system.
- 9.2.17 Rebuild all sizer components to return it to its normal operating conditions.
- 9.2.18 Restore air to the sizer, and if possible check correct operation.

9.3 Results

9.3.1 Pass/Fail/Advise Criteria

If detector 1 is > 5X higher than 4 then FAIL otherwise Pass

If all detectors read < 1000 then Pass

If some detectors read 1000-2500 then ADVISE

If any detectors read >2500 then FAIL

If laser power is >95% and <45% then FAIL

If laser power is between 55% and 95% then Pass

If laser power is between 55% and 45 % then ADVISE

If X50 average is between +2% and -2% of its specified values then PASS otherwise FAIL

If the maximum deviation from the mean size on any measurement is <0.1 microns (0.25%) then PASS, otherwise FAIL

9.3.2 In the event of a failure

9.3.2.1 Check that the procedure was followed correctly

9.3.2.2 Check whether during the procedure any discrepancies with the instrument or its outputs was noted

9.3.2.3 If the x50 is incorrect by a factor of 0.2, 0.25, 0.5, 2, 2.5, or 5 check that the correct matrix was used

9.3.2.4 Re-test the system. In the event of a satisfactory outcome, repeat 1 more time to ensure that the first test was the incorrect one. In the event that the failure repeats, and it cannot be resolved, contact your Xoptix representative. If the following 2 tests are satisfactory, use the average of these tests for the result, and print the records, trend and average pages of all tests, and attach these to the certificate, and detail the issues.

9.4.1 Inspection

9.4.1.1 Dirty Reticle

The reticle should be inspected before each use for fingerprints or other dirty marks. If the reticle does have dirty marks on it then these should carefully be removed using lint free using lint free tissues and ethanol or IPA, **only clean the reticle glass if absolutely necessary.**

9.4.1.2 Damaged Reticle

The reticle should also be inspected before each use for chips and scratches. If you do find chips or scratches check that the reticle has been re-certified and the damage has been recorded on the Reticle Certificate. If the Reticle Certificate does not show the current damage then the reticle should be returned to Xoptix for re-certification.

9.4.2 Service

It is advised that the Xoptix reticle is returned to Xoptix for re-certification at regular intervals – not greater than every 3 years.

9.4.3 Stability

Using the reticle introduces a new component into the systems optical configuration; this can under certain circumstances interact with the flow cell windows to cause reflections that can affect the laser's stability. This will have no effect on the particle size but if you need to check the stability of the laser, using the reticle, it is recommended that you remove the flow cell windows before the test. Remember to replace the windows before running with a real sample.



Type Examination Certificate CML 18ATEX4167X Issue 3

- 1 Equipment intended for use in Potentially Explosive Atmospheres Directive 2014/34/EU
- 2 Equipment **XI and XP Range of In Process Particle Size Analysers**
- 3 Manufacturer **Xoptix Ltd**
- 4 Address **Malvern Hills Science Park
Malvern, WR14 3SZ,
United Kingdom**
- 5 The equipment is specified in the description of this certificate and the documents to which it refers.
- 6 CML B.V., Chamber of Commerce No 6738671, Koopvaardijweg 32, 4906CV Oosterhout, The Netherlands, certifies that this equipment has been found to comply with the Essential Health and Safety Requirements relating to the design and construction of equipment intended for use in potentially explosive atmospheres given in Annex II of Directive 2014/34/EU.
The examination and test results are recorded in the confidential reports listed in Section 12.
- 7 If an 'X' suffix appears after the certificate number, it indicates that the equipment is subject to conditions of safe use (affecting correct installation or safe use). These are specified in Section 14.
- 8 This Type Examination certificate relates only to the design and construction of the specified equipment or component. Further requirements of Directive 2014/34/EU Annex VIII apply to the manufacture of the equipment or component and are separately certified.
- 9 Compliance with the Essential Health and Safety Requirements, with the exception of those listed in the confidential report, has been demonstrated through compliance with the following documents:

EN IEC 60079-0:2018	EN 60079-15:2010	EN 60079-31:2014
---------------------	------------------	------------------
- 10 The equipment shall be marked with the following:



II 3 G D

Ex nR IIC T6 Gc

Ex tc IIC T85°C Dc

Ta = -20°C to +50°C

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R C Marshall
 Operations Manager



CML 18ATEX4167X
Issue 3

11 Description

The XI and XP Ranges of In Process Particle Size Analysers are real time in-process particle size analysers. The analysers consist of either an aluminium (XI ranges) or stainless-steel (XP ranges) enclosure, each available in four sizes (100 mm (2 configurations), 250 mm and 500 mm focal length systems), and a Class 1M 635 nm laser diffraction laser and receiver arrangement, located either side of the sealed process cell.

There are 7 models of each range (7 XI models, plus 7 XP models). In each range the configuration is the same, ie in each range, there are 3 models configured for measurement of dry powders, plus 4 models configured for measurement of particles in liquid suspension.

The main difference in the units from an enclosure perspective, is that the dry systems are normally sold without bulkheads to additionally isolate the sample cell from the laser and detector components. In this case, the seals for the sample cell, form critical components to the integrity of the enclosure.

The liquid configuration is identical, but to protect the laser and detector components from potential liquid leak, these systems have additional bulkhead windows to isolate the sample cell area from the laser and detector modules. In the liquid systems, it is these bulkheads which form the critical sealing components.

The X* Ranges of In Process Particle Size Analysers additionally have either one or two cable gland entries and pneumatic ports to clear condensation within the enclosure. The enclosure may also have side or base plates to allow fixing in location.

The X* Ranges of In Process Particle Size analysers have the following model references:

Aluminium Intellisizer	Stainless steel Pharmasizer
XI220P (100mm focal length lens)	XP220P (100mm focal length lens)
XI550P (250mm focal length lens)	XP550P (250mm focal length lens)
XI1100P (500mm focal length lens)	XP1100P (500mm focal length lens)
XI080L (100mm focal length lens)	XP080L (100mm focal length lens)
XI220L (100mm focal length lens)	XP220L (100mm focal length lens)
XI550L (250mm focal length lens)	XP550L (250mm focal length lens)
XI1100L (500mm focal length lens)	XP1100L (500mm focal length lens)

Where X****P are the dry options and X****L are the liquid suspension options.

Variation 1

This variation introduced the following changes:

- The update of EN 60079-0:2012+A11:2013 to EN IEC 60079-0:2018.

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Version: 3.0 Approval: Approved



CML 18ATEX4167X
Issue 2

12 Certificate history and evaluation reports

Issue	Date	Associated report	Notes
0	30 Jul 2018	R11702A/00	Issue of Prime Certificate
1	06 Jan 2021	-	Re-issue to correct certificate template
2	24 Aug 2021	R14298A/00	Introduction of Variation 1
3	08 Sep 2023	-	Powder coated bodies special condition

Note: Drawings that describe the equipment or component are listed in the Annex.

13 Conditions of Manufacture

The following conditions are required of the manufacturing process for compliance with the certification.

- Where the product incorporates certified parts or safety critical components the manufacturer shall ensure that any changes to those parts or components do not affect the compliance of the certified product that is the subject of this certificate.
- When fitted with Perfluoroelastomer seals, the ambient temperature range marked shall be $-10^{\circ}\text{C} \leq T_a \leq +50^{\circ}\text{C}$ only.

14 Specific Conditions of Use (Special Conditions)

The following conditions relate to safe installation and/or use of the equipment.

- The XI and XP Range of In Process Particle Size Analysers utilise gaskets to maintain a restricted breathing/dust protected enclosure, the enclosure shall only be opened if no explosive gas/dust atmosphere is present. Additionally, the condition of the gaskets shall be reviewed before resealing the equipment.
- The XI Range of In Process Particle Size Analysers utilise a non-metallic cable gland in their construction, these glands are for non-armoured and non-braided cables only and shall be either protected from mechanical damage or the equipment shall be installed in a location having a low risk of impact.
- Under certain extreme circumstances, the non-metallic coating incorporated in the enclosure of this equipment may generate an ignition-capable level of electrostatic charge. Therefore, the equipment shall not be installed in a location where the external conditions are conducive to the build-up of electrostatic charge on such surfaces. In addition, the equipment shall only be cleaned with a damp cloth.

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Certificate Annex

Certificate Number CML 18ATEX4167X
Equipment XI and XP Range of In Process Particle Size Analysers
Manufacturer Xoptix Ltd



The following documents describe the equipment or component defined in this certificate:

Issue 0

Drawing No.	Sheets	Rev.	Approved date	Title
INST8100	1 of 1	1.1	30 Jul 2018	Range of Intellisizers 100mm, 250mm & 500mm (Aluminium)
INST8101	1 of 1	1.1	30 Jul 2018	Typical Intellisizer Body & Eductor Assembly
INST8101-B	1 to 5	1.0	30 Jul 2018	Seal Kit for Sizing System Intellisizer
INST8102	1 of 1	1.2	30 Jul 2018	Seal Kit for Sizing System Intellisizer
INST8103	1 to 5	1.1	30 Jul 2018	Seal Kit for Sample Path - Intellisizer
ORNGATEX8101	1 of 6	1.0	30 Jul 2018	Seal kit for sizing system
INST8051-A	1 to 5	1.1	30 Jul 2018	Seal Kit for Sample Path - Intellisizer
ATEX8000	1 to 2	1.2	30 Jul 2018	Optics & Eductor General Assembly-PharmaSizer (Stainless-steel)
ATEX8001	1 to 3	1.1	30 Jul 2018	Pharma Cell Assembly – Exploded Views
ORNGATEX	1 to 5	001	30 Jul 2018	O-ring Source Data (Intellisizer)
PHORNGATEX	1 to 6	001	30 Jul 2018	O-ring Source Data (Pharmasizer)
DOCU 0130	1 to 5	-	30 Jul 2018	ATEX label details
BODY0060	1 of 1	1.0	30 Jul 2018	Wet One-Piece Fourier Bulkhead
BODY1003	1 to 3	1.4	30 Jul 2018	100mm Intellisizer Body Revised Assembly
BODY1022	1 of 1	1.0	30 Jul 2018	RX/TX Dry Bulkhead Assembly-Pharma
INST8060	1 to 3	1.0	30 Jul 2018	500mm Intellisizer Body & Table Assembly
ORNG8100	1 to 5	1.1	30 Jul 2018	Seal Kit for Sample Path - Pharmasizer

Issue 1

No new drawings

Issue 2

No new drawings

Issue 3

No new drawings

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CML B.V.
Koopvaardijweg 32
4906CV Oosterhout
The Netherlands

Newport Business Park
New Port Road
Ellesmere Port
CH65 4LZ
UK

Evaluation Report (Variation)

Certificate	CML 18ATEX4167X Issue 2
Title	XI and XP Range of In Process Particle Size Analysers
Applicant	Xoptix Ltd
Report	R14298A/00
Date	August 2021

1 Introduction

1.1 Scope of this report and modifications assessed

This report assesses the following modifications to the XI and XP Range of In Process Particle Size Analysers:



- i. The update applied standard EN 60079-0:2012+A11:2013 to EN IEC 60079-0:2018

1.2 Product Description

The product description is unchanged.

1.3 Marking

The marking is unchanged

Item	Detail
Manufacturer name or registered trademark	Xoptix Ltd
Address	Malvern Hills Science Park Malvern WR14 3SZ UK
Type identification	XI* or XP*
Serial No and year of manufacture	xxxx/yy
ATEX certificate number	CML 18ATEX4167X
CE marking and Notified Body No.	 nnnn
ATEX marking	 II 3 G D
Code	Ex nR IIC T6 Gc Ex tc IIIC T85°C Dc
Ambient	Ta = -20°C to +50°C (<i>dependent on seal material</i>)
Rating	6.6 W max.
Warnings/Informative markings	DO NOT OPEN, MAINTAIN OR SERVICE IN AN AREA WHERE AN EXPLOSIVE ATMOSPHERE MAY BE PRESENT

1.4 Applicant's Name & Address

The Applicant is unchanged

1.5 Manufacturer's Name & Address

The Manufacturer is unchanged

1.6 Trademark

There is no change to the Trademark

1.7 Equipment name/model number

XI* or XP*

1.8 Rating

The product rating is unchanged.

1.9 Assessment Standards

The standards have been updated. The full list of standards is shown below:

EN IEC 60079-0:2018

EN 60079-15:2010

EN 60079-31:2014

1.10 Documentation

1.10.1 Technical Documents

The manufacturer's drawings are unchanged as a result of this variation.

1.10.2 Supporting information

There is no supporting information used for this variation.

1.11 Instructions

The modifications required the instructions to be revised. Updated instructions complying with EN IEC 60079-0:2018, clause 30, for the modified product, were provided.

1.12 Attachments

None.

1.13 Conditions of manufacture

There are no additional conditions of manufacture. Any existing conditions of manufacture are unchanged.

1.14 Specific Conditions of Use/Schedule of Limitations

There are no additional conditions/limitations. Any existing conditions/limitations are unchanged.

1.15 Compliance with Essential Requirements of Directive 2014/34/EU and Directive UKSI 2016:1107 (as amended)

There have been no changes affecting the original assessment to the Essential Health & Safety Requirements of Directive 2014/34/EU.

1.16 Conclusion

The modifications assessed in this report allow the equipment to maintain compliance with the listed standards, the certification code being unchanged. In addition, the equipment continues to meet the requirements of European Directive 2014/34/EU, for the Category indicated in section 1.3.

1.17 Signatories

Compiled by + signature (ExTL):

A. Smith
Senior Certification Engineer



Reviewed by + signature (ExTL):

R. C. Marshall
Operations Manager



Approved by + signature (ExCB):

Date: 24 Aug 2021
R. C. Marshall
Operations Manager



Date: 24 Aug 2021

2 Certification Overview

See 3.1.1

3 Modifications

3.1 Assessment of modifications

3.1.1 The update of EN 60079-0:2012+A11:2013 to EN IEC 60079-0:2018

The table below identifies the changes made between EN 60079-0:2012+A11:2013 and EN IEC 60079-0:2018.

EN IEC 60079-0:2018			
Clause	Requirement – Test / Changes	Remark	Verdict
Multiple	Throughout document, "electrical equipment" replaced by "equipment" where appropriate	Minor and/or editorial change	-
1	Scope List of "Type of "Protection" and "Product" standards combined into one list	Minor and/or editorial change	-
3	Definitions used in multiple sub-parts added. Definitions harmonized across sub-parts and added to 60079-0 where appropriate. Battery definitions updated	Minor and/or editorial change	-
5.1.2	Clarification of the way that information on process temperature influences can be expressed	Minor and/or editorial change	-
5.2	Clarification regarding the determination of service temperatures when dust layers are present	Minor and/or editorial change	-
5.2	Clarification on the need to provide service temperature information for Ex Components in the Schedule of Limitations	Minor and/or editorial change	-
5.3.2.3.1	Relocation of EPL Da dust layer requirements from IEC 60079-18 & IEC 60079-31	Minor and/or editorial change	-
b)	Clarified that for EPL Db, a maximum specified dust layer of greater than 200 mm is not permitted as thicker layers have no additional effect on maximum surface temperature	Minor and/or editorial change	-

EN IEC 60079-0:2018			
Clause	Requirement – Test / Changes	Remark	Verdict
c)	Added for EPL Db, a dust layer in a specified orientation, marked as T_L	Extension Product has been tested in accordance with 5.2.3.1 a)	PASS
5.3.2.3.3	Clarified that for EPL Dc, no dust layer tests are required.	Minor and/or editorial change	-
5.3.3	Clarified that the “temperature” is the temperature of the air surrounding the component	Minor and/or editorial change	-
5.3.4	Subdivided section dealing with higher permitted surface temperatures for “smooth” surfaces. Corrected area from 1,000 mm ² to 10,000 mm ²	Minor and/or editorial change	-
6.1	Clarified that the “Ex” requirements of IEC 60079 supplement those of the relevant industrial standards	Minor and/or editorial change	-
6.5	Added requirement that where an adhesive is used to secure a gasket, it shall be used within its COT and shall comply with the requirements for cements	Where applicable, the OEM certification details service temperature limits	PASS
former 6.6.2	Requirements relocated to IEC 60079-28	Minor and/or editorial change	-
6.6.3	Ultrasonic requirements updated based on latest research work	Minor and/or editorial change	-
6.6.4	Added reference to IEC 60079-28	Minor and/or editorial change	-
7.1.2.2	Material identification parameters have been revised to reflect reasonably obtainable information	Minor and/or editorial change	-
7.1.2.2	“RTI-mechanical” has been clarified to include “RTI- mechanical strength” and “RTI-mechanical impact”	Minor and/or editorial change	-
7.1.2.3	Material identification parameters have been revised to reflect reasonably obtainable information	Minor and/or editorial change	-
7.1.2.4	Relocated information on “cements” from Clause 12.	Minor and/or editorial change	-

EN IEC 60079-0:2018			
Clause	Requirement – Test / Changes	Remark	Verdict
7.2.2	"RTI-mechanical" has been clarified to include "RTI- mechanical strength" and "RTI-mechanical impact". Requirements for cements aligned with the requirements for elastomers.	Minor and/or editorial change	-
7.2.2	Relocation of 10 K margin for EPL Gc or Dc from IEC 60079-15, IEC 60079-18 & IEC 60079-31	The product has not been assessed as compliant with the standards detailed	N/A
7.3	Added clarification with respect to gaskets and seals where only the outer edge is potentially exposed to light.	Minor and/or editorial change	-
7.4.2	Clarification added that one or more of the described techniques may be used	Minor and/or editorial change	-
7.4.2 b)	Added additional relaxation for the case where a surface is in contact with an earthed surface on only two of four sides.	The product is not intended for use where there is the risk of there being an external electrostatic charging mechanism	N/A
7.4.2.c)	Added reference to IEC 60243-1 and IEC 60243-2 for test method to require a 4 kV DC test.	See 7.4.2 b)	N/A
7.4.2 e)	Additional guidance added with respect to the possible Specific Conditions of Use	See 7.4.2 b)	N/A
7.4.2 f)	New option added for portable, mains-powered equipment with earth-connected guard	See 7.4.2 b)	N/A
7.4.2 g) Table 10	Added option for determination of maximum transferred charge.	See 7.4.2 b)	N/A
7.4.3 a)	Added missing limits (same as 7.4.2)	Minor and/or editorial change	-
7.4.3 b)	Clarified that it is a dc test that is conducted	Minor and/or editorial change	-
7.5	Clarified that this requirement is not applied to personal or portable equipment	Minor and/or editorial change	-
8.2	Clarified Group I limits	Minor and/or editorial change	-
8.3	Clarified Group II, EPL Ga limits	Minor and/or editorial change	-
8.5	Added limitation for external surfaces of > 65% copper	The product does not utilise enclosures containing more than 65% copper	N/A

EN IEC 60079-0:2018			
Clause	Requirement – Test / Changes	Remark	Verdict
9.1	Added clarification as to what is considered a tool	Minor and/or editorial change	-
9.4	Clarified that the tolerance class of the set screw is not critical, only that it does not protrude from the threaded hole after tightening	Minor and/or editorial change	-
12	Information on cements transferred to Clause 7	Minor and/or editorial change	-
13.5	Required that Ex Component Certificates require a Schedule of Limitations in all cases	The product is not a component	N/A
14	Revised to clarified that all connection facilities may not be a "Compartment"	Minor and/or editorial change	-
15.3 15.4	Sub-clause split to separate the requirements for protective earthing and equipotential bonding into separate sections	Minor and/or editorial change	-
15.6 15.7	Section split to separate secureness of electrical connections from the internal earth continuity plate	Minor and/or editorial change	-
16.3	Non-threaded Group I cable glands are no longer required to be Ex Components	The product is not a cable gland	N/A
16.4	Non-threaded Group I blanking elements are no longer required to be Ex Components	See 16.3	N/A
17	Scope of Clause 17 clarified to define applicability	Minor and/or editorial change	-
17.3	Additional guidance notes added to address bearings	Minor and/or editorial change	-
18.2	Clarified applicability to disconnectors, interlocks, and maintenance switches	Minor and/or editorial change	-
19	Fuse requirements deleted as they are addressed in the individual sub-parts	Minor and/or editorial change	-
20.1	Added requirements for EPL Gc and Dc	The product is not and does not contain external plugs, socket outlets or connectors for field wiring	N/A

EN IEC 60079-0:2018			
Clause	Requirement – Test / Changes	Remark	Verdict
20.2	The test circuit requirements for a flameproof connection have been removed as they are more completely specified in IEC 60079-1	Minor and/or editorial change	-
21.1 Table 15	The impact test requirements for luminaires are relocated to Table 15	Minor and/or editorial change	-
21.2	Clarified interlock switch operation for flameproof luminaires	Minor and/or editorial change	-
23.2	Clarified that some Types of Protection permit connection of cells in parallel	Minor and/or editorial change	-
Table 13	New cell types and data added based on latest available data	The product does not contain cells or batteries	N/A
Table 14	New cell types and data added based on latest available data	See Table 13	N/A
24	Clarification of what documentation is to be prepared regarding the explosion safety aspects of the equipment	Minor and/or editorial change	-
26.2	Clarification that the type tests are to take into consideration the installation instructions	Minor and/or editorial change	-
26.4.1.1	Clarification that the "glass" requirements also apply to "ceramic" parts	Minor and/or editorial change	-
26.4.1.2.2 26.4.1.2.3	Added a permission to interchange the order of tests at the "lower test temperature" and the "upper test temperature".	Minor and/or editorial change	-
26.4.2	Clarified the construction of the impact test fixture	Minor and/or editorial change	-
26.4.2	Clarified the impact tests for glass parts	Minor and/or editorial change	-
26.4.5.1	Added clarification to deal with the new IPX9 ratings	The product does not provide IPX9 ingress protection	N/A
26.5.1.3	Clarified the test voltage for maximum surface temperature	Minor and/or editorial change	-
26.5.1.3	Relocation of EPL Da dust layer requirements from IEC 60079-18 & IEC 60079-31	The Ex ec Auxiliary Terminal Boxes are not intended for use where the source of hazard is combustible dust	N/A
26.5.1.3	Relocation of EPL Db specified dust layer requirements from IEC 60079-31	Minor and/or editorial change	-

EN IEC 60079-0:2018			
Clause	Requirement – Test / Changes	Remark	Verdict
26.5.1.3	Added for EPL Db, a dust layer in a specified orientation, marked as T_L	See 5.2.3.1 c)	N/A
26.5.1.3	Clarified that for EPL Dc, the testing is conducted without a dust layer.	Minor and/or editorial change	-
Table 17	Relocation of thermal endurance to heat 10 K relaxation for Gc equipment from IEC 60079-15, IEC 60079-18, & IEC 60079-31	Minor and/or editorial change	-
26.10	Clarification of a consistent way to address elastomeric materials exposed to ultraviolet light	Minor and/or editorial change	-
26.11	Replacement of "oil No. 2" with the revised designation of "oil IRM 902"	Minor and/or editorial change	-
26.13	Option added for testing at lower voltages when low resistance materials are encountered	The product does not utilise plastic enclosures	N/A
26.17	Transferred charge test added based on IEC TS 60079-32-2	See 26.13	N/A
29.3 e)	The reference to a specific instruction document instead of an "X" condition relocated to e) instead of a note giving a permission	Minor and/or editorial change	-
29.4 b)	Updated to reflect the additional levels of protection already shown in the sub-parts: "da", "dc", "eb", "ec", "oc", "op is", "op pr", "op sh", "pxb", "pyb", "pzc", "qb", "sa", "sb", and "sc"	Minor and/or editorial change	-
29.4	Text added to address marking of "Ex associated equipment"	The product is not associated apparatus	N/A
29.5 b)	Updated to reflect the additional levels of protection already shown in the sub-parts: "ic", "op is", "op pr", "op sh", "pxb", "pyb", "pzc", "sa", "sb", and "sc".	Minor and/or editorial change	-
29.5 d)	Clarified marking of EPL Da, EPL Db with no dust layer, EPL Db with a specified dust layer, and EPL Dc	Minor and/or editorial change	-
29.5 d)	Introduced marking for EPL Db with a dust layer in a specified orientation	See 26.5.1.3	N/A

EN IEC 60079-0:2018			
Clause	Requirement – Test / Changes	Remark	Verdict
29.5	Text added to address marking of "Ex associated equipment"	See 29.4	N/A
29.9	Text added to address marking of equipment intended to be installed in a boundary wall	The product is not intended for mounting in a boundary wall	N/A
29.10	The marking of Ex Component enclosure was aligned with the marking requirements of IEC 60079-1 and IEC 60079-7	Minor and/or editorial change	-
former 29.13	The alternate marking of EPL has been deleted	Information only	-
29.15	Marking for electric machines operated with a converter clarified	Minor and/or editorial change	-
30.1	Instruction material guidance clarified	Minor and/or editorial change	-
30.3	Additional instruction material for electric machines added	The product is not an electrical machine	N/A
30.5 A.5	Additional instruction material for cable glands added	The product is not a cable gland	N/A
A.1	Allow ISO 10807 hose assemblies to be used with cable glands	See 30.5	N/A
A.3	Clarify testing with stainless steel mandrels	See 30.5	N/A
A.3.1.1	Reduction of the time / slippage permitted	See 30.5	N/A
A.3.3 Figure A.3	Clarify impact testing of cable glands	See 30.5	N/A
A.3.4	Clarified the order of tests	See 30.5	N/A
Annex B	Clarified remarks	Minor and/or editorial change	-
Figure C.1	Aligned Figure with text	Minor and/or editorial change	-
Annex D (informative)	Clarified operation of electric machines from converters	Minor and/or editorial change	-
Annex E (informative)	Clarified temperature testing of electric machines	Minor and/or editorial change	-
Annex G (informative)	Flowchart for Cable Gland testing	Minor and/or editorial change	-
Annex H (informative)	Guidance of electric machine shaft voltages	Minor and/or editorial change	-

4 Test Summary

No samples were received, and no tests were conducted.



Newport Business Park
New Port Road
Ellesmere Port
CH65 4LZ
UK

Evaluation report (UKEX based on ATEX)

Certificate	CML 21UKEX4843X
Title	XI and XP Range of In Process Particle Size Analysers
Applicant	Xoptix Ltd
Report	R14298B/00
Date	September 2021

1 Introduction

Note: This report may include the assessment completed in support of the issue of a Category 1 or 2 UK Type Examination Certificate, or it may include the assessment completed in support of the issue of a Category 3 Type Examination Certificate (for the UK).

As Category 3 certificates are referred to as Type Examination Certificates in both the UK and the EU, in order to distinguish between the certificate issued by a European Notified Body (NB) and the certificate issued by CML as the UK Approved Body (AB), throughout this report, for all Categories, the certificate issued by an NB is referred to as an 'ATEX' certificate and the certificate to be issued by the AB is referred to as a 'UKEX' certificate.

1.1 UKEX certificate to be issued

The following UKEX certificate is to be issued by Eurofins E&E CML Limited based on an ATEX certificate issued by CML B.V. and to undergo the modifications listed in Section 1.1.1, as applicable.

Product	ATEX Certificate Number and Issue	UKEX Certificate Number
XI and XP Range of In Process Particle Size Analysers	CML 18ATEX4167X, Issue 2	CML 21UKEX4843X

Wherever 'previous associated reports' are mentioned in this report, this refers to the evaluation reports which have contributed to the issue of the ATEX certificate on which the UKEX certificate is based.

1.1.1 Modifications assessed

In addition to the issue of a new UKEX certificate, as specified in Section 1.1, the following modification has been introduced:

- Update of the marking label to include the additional information required for the UKEX approval.

Refer to section 1.3 for marking details.

1.1.2 Scope of this report

This report is intended to be used as the basis for the subsequent certification of the product listed in Section 1.1 against the standards referred to in Section 1.9. The assessment applies to the certified code and ambient/service temperature range shown on the related ATEX certificate, and atmospheric conditions in the range of 80 to 110 kPa, with up to 21% oxygen. Throughout this report, a point is used as the decimal separator.

1.2 Description

There have been no changes to the description of the product. Refer to the previous associated reports.

1.3 Marking

In addition to the marking shown in the previous associated reports, the products are also marked with the following.

Item	Detail
UKEX Certificate number	CML 21ATEX4843X

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Item	Detail
UKCA mark	

1.4 Applicant's name & address

The applicant's name & address are unchanged. Refer to previous associated reports.

1.5 Manufacturer's name & address

The manufacturer's name & address are unchanged. Refer to previous associated reports.

1.6 Trademark

The trademark is unchanged. Refer to previous associated reports.

1.7 Equipment name/model number

The equipment name/model number are unchanged. Refer to previous associated reports.

1.8 Ratings

The ratings are unchanged. Refer to previous associated reports.

1.9 Assessment standards

The assessment standards for the UKEX certification are the same as those used for the associated ATEX certification.

1.10 Documentation

1.10.1 Technical documents

The drawing listed below shows the revised marking label that is to be applied to the product. All other drawings are unchanged from the most recent ATEX approval. Refer to the approval listed in Section 1.1.

For all other aspects of the equipment relating to compliance with the listed certification standards, reliance is placed on the related ATEX certification, refer to previous associated reports.

Drawing No	Sheets	Rev	Approved date	Title
DOCU 0130	1 to 5	3	03 Sep 2021	Project CML 18ATEX4167X ATEX Label information

1.10.2 Supporting information

Document	Title
Instructions	In-Process Particle Size Analyser (Including IntelliSizer Options) User Manual

1.10.3 Instructions

The manufacturer supplied a copy of the instruction details that confirms compliance with EN IEC 60079-0:2018, clause 30, and any other applicable standards as listed on the certificate. A copy is retained on file.

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1.11 Attachments

None.

1.12 Conditions of manufacture

Any conditions of manufacture are as per the related ATEX certificate.

1.13 Specific conditions of use / Schedule of limitations

Any conditions/limitations are as per the related ATEX certificate.

1.14 Compliance with essential requirements of Directive UKSI 2016:1107

The assessment conducted to Directive 2014/34/EU under the associated ATEX approval was accepted as also meeting the Essential Health & Safety Requirements of Directive UKSI 2016:1107 (as amended) for the UKEX certification, for the category marked on the product.

1.15 Conclusion

The equipment referred to in this report satisfies the requirements of the standards listed on certificate CML 18ATEX4167X, Issue 2, the relevant certification code being as indicated on CML 18ATEX4167X, Issue 2. The tests and assessments are limited to the standards aforementioned.

The equipment identified in this report is recommended for certification by the signatories.

1.16 Signatories

Compiled by + signature (ExAB): **M. Gibbons**
Certification Engineer



Approved by + signature (ExAB): **L. A. Brisk**
Certification Officer



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2 Certification overview

The product listed in section 1.1 is to be issued with a Eurofins E&E CML Limited UKEX certificate based on an ATEX certificate issued by CML B.V.

This report is to be read in conjunction with the reports listed on all issues of the ATEX certificate specified in Section 1.1.

As part of this assessment, where necessary, the latest technical documents contributing to the related ATEX certificate have been recognised and updated. Refer to Section 1.10.

All previous test data and assessments have been reviewed and are considered acceptable for UKEX Certification.

3 Documentation checklist

The following information was obtained, and all documentation is held in the Eurofins E&E CML Limited project file:

Item	Checked	Additional Comments
Label drawings showing the UKCA symbol, the UK Approved Body number and the UKEX certificate number (as applicable; refer to section 1.3).	✓	Refer to section 1.3.
Updated manual showing the new UKEX certificate number and marking details.	✓	

The UKEX certification is based on a CML B.V. ATEX certification. All documentation contributing to the issue of the CML B.V. ATEX certificate is held in the certification file for the ATEX certificate, which is available to Eurofins E&E CML Limited.

4 Verification checklist

The following was verified, to support the UKEX certification by Eurofins E&E CML Limited:

Aspect to be verified	Checked	Additional Comments
The information on the manufacturer's drawings supporting the UKEX approval (which is critical to showing the product's compliance) is identical to the information on the drawings used in support of the issue of the original ATEX certificate.	✓	The drawings approved for ATEX are relied upon.
The equipment's marking is identical to the previous approval, except for the marking of the UKCA symbol, Approved Body number and UKEX certificate number (as applicable; refer to section 1.3).	✓	
All technical information on the UKEX certificate is identical to the original ATEX certificate, or there is a suitable reference on the UKEX certificate showing	✓	

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Aspect to be verified	Checked	Additional Comments
where the information can be located on the ATEX certificate.		
All relevant information which was used in support of the original certification is held by Eurofins E&E CML Limited.	✓	Refer to section 3

5 Assessment of modifications

5.1 Marking

The label drawing listed in Section 1.10.1 has been updated to include the additional information required for the UKEX approval. All other marking remains the same as was previously approved under the related ATEX certification. No further assessment was considered to be necessary.

6 Test summary

No tests were conducted as part of this approval. All test details are covered by the previous associated reports linked to the ATEX certificate.

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