# AccuSizer<sup>™</sup> Syringe Injection Sampler SIS

Field service manual





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## **DOCUMENT CHANGE HISTORY**

DATE	DESCRIPTION OF DOCUMENT REVISION OF REVIEW	NEW RELEASE NUMBER
10/19/2016	(Software Version 2.1.1.13-14) Manual Version	
09/13/2016	(Software Version 2.1.1.15+) Manual Version	- 02
11/28/2017	(Software Version 2.4.2.1+) Manual Version	- 03
04/10/2018	(Software Version 2.5.4.3+) Manual Version	- 04
09/01/2018	(Software Version 2.6.3.1+) Manual Version Reformat of Installation Guide into Field Service Manual	- 05
	Addition of the following information:	
	General Information	
	Health and Safety	
	<ul> <li>Unpacking and Installation</li> </ul>	
	System Performance	
	• Features of Fluidics	
	Maintenance Procedure	
	• Troubleshooting	
12/3/2025	(Software version 3.1.6.0) Manual Version	- 08
	Rebranded and updated logos, contact information	

## **NOTICES**

## ENTEGRIS, INC.

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## MANUAL PART NUMBER

998-006

## **EDITION**

(Software Version 2.1.1.13-14) Manual Version (Software Version 2.1.1.15+) Manual Version - 02 (Software Version 2.4.2.1+) Manual Version - 03 (Software Version 2.5.4.3) Manual Version - 04 (Software Version 2.6.3.1) Manual Version - 05 (Software Version 3.1.5.1) Manual Version - 07 (Software Version 3.1.6.1) Manual Version - 08

## WARRANTY

Entegris makes every effort to ensure that this document is correct. However, due to Entegris policy of continual product development, we are unable to guarantee the accuracy of this, or any other document after the date of publication. We therefore disclaim all liability for any changes, errors or omissions after the date of publication. No production or transmission of any part of this publication is allowed without express written permission of Entegris.

## TECHNOLOGY LICENSES

The hardware and/or software described in this document are furnished under a license and may be used or copied only in accordance with the terms of such license.

## SIGNAL WORD DEFINITIONS

The following symbology is used throughout this user manual next to hazard information:



▲ WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

NOTE: Indicates a statement of policy directly or indirectly related to personnel safety or property protection.

## GENERAL INFORMATION

#### **SUPPORT**

If you need technical assistance, contact Entegris based on the type of support needed.

## **Technical Support**

Entegris, Inc. 7225 W Oakland Street Chandler, AZ 85226

T: (727) 846-0866

Expedited Instrumentation Technical Assistance Entegris

## **USER MANUAL**

The AccuSizer™ User Manual (Manual Part Number 998-002) is accessible from the software and a hard copy is provided with the instrument upon delivery. Additional hard copies of the user manual may be obtained from Entegris upon request.

## SUPPLEMENTAL READING

More details on the operation of the instrument can be found in the following manuals:

Title	Part number
AccuSizer™ Theory	998-001
AccuSizer™ SIS Calibration using AccuSizer™ Software Manual	992-015

#### SAFETY RELATED POLICY

Entegris will provide end user information about any safety related upgrades or newly identified hazards with the AccuSizer SIS should it become necessary.

The end user and their subcontractors who work with the AccuSizer SIS must ensure that their respective employees are provided with material safety data sheets from their Environmental Health and Safety (EHS) department for all chemicals that pass through the AccuSizer SIS. The end-user is responsible for checking that the instrument components of the AccuSizer SIS are compatible with their process before use; see the Appendix for more information on instrument specifications.

It is imperative that when working on any piece of equipment, the service technician follows all policies, practices, and procedures established by the end users' EHS group.

## **DECONTAMINATION AND DISPOSAL**

To clean the AccuSizer SIS Fluidics system, flush DI water through each flow path using software controls or manually. If hazardous chemicals were used in the system, use proper decontamination procedures.

Do not dispose of the AccuSizer SIS or its components in the trash. Properly dispose of the unit with an electronics waste management system according to local policies. Before disposing the unit, contact Entegris for instructions on disabling the unit from being powered on again.

## SAMPLE HANDLING WARNINGS

Always handle all substances in accordance with the COSHH regulations (UK) or any local regulations concerning sample handling safety. The Material Safety Data Sheets (MSDS) must be obtained for all substances used in the system and safety precautions and control measures used accordingly.

Use the instrument in a well-ventilated room if noxious samples or dispersants are to be analyzed.

Wear a protective respiratory mask if noxious samples or dispersants are being handled, particularly in their dry state during sample preparation.

Wear protective gloves when handling hazardous materials, or those that cause skin infections or irritations. Chemical protection gloves are suitable, which are tested according to EN 374. At least 4 mil thick. Type of material PVC: polyvinyl chloride, PE: polyethylene, NR: natural rubber, latex, CR: chloroprene (chlorobutadiene) rubber, NBR: acrylonitrile-butadiene rubber, IIR: isobutene-isoprene (butyl) rubber, FKM: fluoro-elastomer, PVA: polyvinyl alcohol, Nitrile. Gloves should be used in accordance with the instructions provided by the PPE supplier, except where additional instructions by the equipment supplier are required.

Always test a sample for chemical compatibility before using in the instrument.

After measuring a hazardous sample scrupulously clean the instrument to remove any contaminants before making another measurement.

Always label samples for analysis using industry standard labeling, particularly if they are handled by a number of staff or stored for long periods. Clearly mark any operator hazard and associated safety precautions that are required for the handling of dangerous materials.

Always adopt responsible procedures for the disposal of waste samples. Many chemicals are forbidden by law to be disposed of in such a manner as to allow their entry into the water system. The user is advised to seek local advice as to the means available for disposal of chemical wastes in the area of use. Recommendations can be found in the Safety Data Sheets.

The surfaces of the instrument may be permanently damaged if samples are spilt onto them. If a spill occurs, then the instrument should be disconnected from the power supply before cleaning.

#### **REAGENTS USED**

The user is responsible for the chemicals put through the system that come from their own process. Entegris may supply a polystyrene latex (PSL) standard with the system for verifying particle size accuracy performance:

Thermo Scienific Polymer Microsphere Suspension which is defined as non-hazardous based on its SDS. It contains the following chemistries:

- a. Polystyrene 1% (CAS no. 9003-53-6) or Polystyrene divinylbenzene 1% (CAS no. 9003-70-7)
- b. Sodium azide <0.09% (CAS no. 26628-22-8)

## INTRODUCTION

This Field Service Manual is designed to enable the user to set up the system and perform initial operational checks. In addition, routine maintenance procedures are described and all the physical features of the instrument are identified and explained.



WARNING: This instrument or the samples to be measured may be hazardous if misused. You must read the Health and Safety chapter of this manual before operating the system.

## INSTRUMENTATION

This manual addresses the following AccuSizer instruments:

INSTRUMENT NAME	MODEL NUMBER
AccuSizer Syringe Injection	on Sampler (SIS) which includes:
AccuSizer SIS Fluidics module	AccuSizer A7000 SIS
AccuSizer Counter	AccuSizer A7000 Counter
Sensor (SPOS)	LE Series sensor

## ASSUMED INFORMATION

This manual will assume that you are installing and using an AccuSizer Syringe Injection Sampler (SIS). If there are any operational procedures that differ for any of the other instruments in the range then alternative information will be provided.

This manual will refer to the above instruments as either the "AccuSizer SIS" or the "Instrument".

## **SECTION DESCRIPTIONS**

The following is a list of the contents and objectives of the sections within this manual.

## Health and Safety

Essential information that should be read to ensure the safe operation of the instrument.

## Unpacking and installation

The method of unpacking and installing the instrument is covered. It should be noted that installation of the instrument MUST be done by Entegris personnel. Damage could be caused to the instrument if initial installation is undertaken by the user. This section should be used as a source of reference in the event that the instrument location is changed.

## System Performance

Once installed, it is useful for the user to ensure that the instrument is functioning at it's optimum performance.

#### Features of the Fluidics

This will aid the user in becoming familiar with the features of the instrument fluidics.

## Maintenance Procedure

The instrument will function at optimum performance when maintained on a regular basis. This section outlines the maintenance procedures that the operator and supervisor of the instrument are expected to perform.

## **Troubleshooting**

This will aid the user in troubleshooting the instrument on their own. If these remedies do not work, Entegris should be contacted.

## **HEALTH AND SAFETY**

Following are the safety guide-lines that apply to the AccuSizer Syringe Injections Sampler (SIS) instrument. The guidelines are part statutory and part advisory. They should not be used as a replacement for common sense by the user.

This instrument contains no user serviceable parts except the fluidics which encompasses all tubing, syringes and laser light sensors. Repairs should be left to a qualified Entegris representative. The maintenance section of this manual describes all the operations that are required for correct routine operation.



MARNING: If this equipment is used in a manner not specified within this manual, the protection provided by the equipment may be impaired.

## **INSTRUMENT ACCESS**

Within this manual reference is made to the various people that will have access to the instrument. Below is a list of these people and their responsibility:

## **Entegris Employees**

Entegris personnel (service engineers, representatives etc.) have full access to the instrument and are authorized to perform all service procedures that may be required.

## Supervisor

The supervisor is the person responsible for the management/safety of the instrument and of its operation. The supervisor is responsible for the training of the operators. The supervisor can perform all user maintenance routines identified at the end of this manual, including changing the fuses.

## Operator

An operator is a person trained in the use of the instrument. The operator can perform all user maintenance routines identified at the end of this manual, except changing the fuses.

## SITE REQUIREMENTS

Specific site requirements must be met to ensure the safe operation of the AccuSizer Syringe Injection Sampler (SIS) instrument. Information about the site requirements can be found in the next section of this manual.



MARNING: If the instrument is used in an environment not conforming to the site requirements, safety and/or performance may be compromised.

## **ACCUSIZER SENSOR LASER SAFETY PRECAUTIONS**



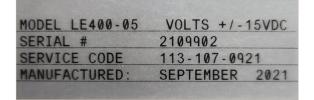
MARNING: Laser radiation can be harmful to the body and can cause permanent eye damage. Read this section of the manual carefully before operating the equipment.



▲ WARNING: Performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

The AccuSizer Model LE400-05 Sensor is certified to conform to the applicable requirements of 21 CFR Subchapter J, 1040.10 and 1040.11 (Radiation Control for Health and Safety Act of 1968, 42 U.S.C. 263f) and IEC 60825-1 and IEC 61010-1.

As presently constructed, each of these sensors is designated by the Center for Devices and Radiological Health (CDRH) as a Class I product, resulting in exposure to negligible levels of Laser Radiation during normal operation. The two labels shown below are affixed to the sides of the LE400-05 Sensor. They attest to the above Safety Certification and also establish the place and date of manufacture of each sensor.



THIS EQUIPMENT CONFORMS TO PROVISIONS OF US 21 CFR 1040.10 AND 1040.11



WARNING: Read carefully before attempting to operate any AccuSizer System, including, but not limited to, the AccuSizer Syringe Injection Sampler (SIS).

No Laser Radiation is accessible anywhere in the immediate outside vicinity of any sensor listed above whenever power is delivered to the sensor (typically from an AccuSizer system). Each sensor is sealed at the factory and must remain sealed when in possession of the operator, whether it is in operation or not. The black-anodized aluminum outer housing of the sensor constitutes a Protective Housing, which prevents the operator's access to laser radiation as long as the top cover and main body of the sensor are securely attached to each other.



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

During operation the Top Cover of the sensor Must Remain Attached to the Main Body – i.e., the Sensor Must Remain Sealed – by means of the 4 screws secured at the factory. The DANGER label on the cover, reproduced below, warns of the user's possible exposure to the laser beam (25 milliwatts, 785 nm wavelength) if the Top Cover and Main Body of the sensor are detached for any reason while power is applied to the unit.

#### DANGER

LASER RADIATION WHEN OPEN. AVOID DIRECT EXPOSURE TO BEAM.

RAYONNEMENT LASER SI OUVERT. ÉVITER TOUTE EXPOSITION DIRECTE AU FAISCEAU.



MARNING: Separation of the top cover and main body of the sensor while power is applied to the sensor may result in possible Direct Exposure to Dangerous Laser Radiation and is Prohibited.

## **ELECTRICAL SAFETY WARNINGS**

- The AccuSizer is mains powered and its input power cables should be treated accordingly.
- The metal parts of the instrument are earthed via a protective earth connection. Never run the equipment without a protective earth connection.
- Do not obscure any electrical sockets ensure that all electrical plugs can be disconnected in an emergency.
- · Route electrical cables away from areas where liquids may be spilt.
- · Be careful when measuring samples to avoid liquid or powder spillages over the equipment. Conducting materials or liquids can break down the insulation and cause hazardous conditions within the instrument. Should such spillages occur, disconnect the power and clean immediately.

## SAMPLE HANDLING WARNINGS

• Always handle all substances in accordance with the COSHH regulations (UK) or any local regulations concerning sample handling safety. The Material Safety Data Sheets (MSDS) must be obtained for all substances used in the system and safety precautions and control measures used accordingly.

- Use the instrument in a well ventilated room if noxious samples or dispersants are to be analyzed.
- Wear a protective respiratory mask if noxious samples or dispersants are being handled, particularly in their dry state during sample preparation.
- Do not smoke during measurement procedures, particularly where inflammable or toxic samples or dispersants are used or stored.
- Do not eat during measurement procedures, particularly where poisonous samples or dispersants are used or stored.
- Wear protective lab eyewear, lab coat and gloves when handling hazardous materials, or those that cause skin infections or irritations.
- Take care when handling glass. Hazardous materials may enter a wound caused by broken glass.
- Always test a sample for chemical compatibility before using in the instrument. Refer to Appendix A at the end of this manual that lists all substances that are compatible with the AccuSizer SIS Fluidics and LE sensor.
- After measuring a hazardous sample scrupulously clean the instrument to remove any contaminants before making another measurement.
- Always label samples for analysis using industry standard labeling, particularly if they are handled by a number of staff or stored for long periods. Clearly mark any operator hazard and associated safety precautions that are required for the handling of dangerous materials.

NOTE: It is important to keep a record of all hazardous substances used in the instrument for the protection of Service and Maintenance personnel.

- Always adopt responsible procedures for the disposal of waste samples. Many chemicals are forbidden by law to be disposed of in such a manner as to allow their entry into the water system. The user is advised to seek local advice as to the means available for disposal of chemical wastes in the area of use. Recommendations can be found in the Safety Data Sheets.
- The surfaces of the instrument may be permanently damaged if samples are spilt onto them. If a spill occurs then the instrument should be disconnected from the power supply before cleaning.

## MOVING THE INSTRUMENT

If it is necessary to move the instrument the following guidelines should be followed:

- Drain the AccuSizer SIS fluidics of all liquids.
- Disconnect the AccuSizer Counter from the power source
- Disconnect the AccuSizer SIS fluidics from the AccuSizer Counter.
- Disconnect the AccuSizer Counter from the computer.
- Disconnect the computer from the power source.
- Disconnect the LE sensor from the AccuSizer Counter.

It is recommended that at least two people are used to move the instrument to a cart that can be moved to the new location. Always adopt proper lifting techniques to avoid back injury. Please refer to the Lifting and Carrying instructions found in the Unpacking and Installation section of this manual.

If the instrument is to be moved long distances, it is recommended that it is repackaged in its original packaging. This also applies to all accessories. Repackaging is the reverse of the unpacking procedure described in the Unpacking and Installation section of this manual.

NOTE: If the instrument is to be returned for any type of service, health and safety information must be enclosed for all samples that were measured on the instrument.

## DISPOSING OF THE INSTRUMENT

When the need eventually arises to dispose of the instrument, it should be done in a responsible manner. The following are guidelines that should be followed:

- Before disposal of the instrument, it should be disabled in such a manner as to make it impossible for it to be powered up. Seek advice from your local Entegris representative for details.
- · The instrument should be decontaminated if hazardous materials have been used in it
- Refer to any local regulations on disposal of equipment.



WARNING: Do not dispose of the instrument in the trash.

#### UNPACKING AND INSTALLATION

The AccuSizer Syringe Injections Sampler (SIS) instrument is only to be installed by Entegris personnel or its representative. However, the following information is aimed at providing guidance in unpacking the instrument, selecting the appropriate site and connecting the instrument. If, in the future, the instrument is to be moved, refer back to these directions.

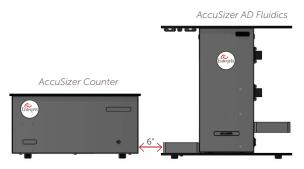
The AccuSizer Syringe Injections Sampler (SIS) is delivered in two boxes; one containing the AccuSizer SIS Fluidics, along with documentation and accessories and the second containing the AccuSizer Counter along with the LE Sensor, and cables.

## **ENVIRONMENTAL CONDITIONS**

The selection and preparation of a suitable site prior to unpacking will help to ensure trouble free operation and will be reflected in the quality of the results. The equipment is designed and intended for use within a normal laboratory environment with the following conditions recommended;

- Humidity <50%.
- Temperature, between 5 and 35 degrees Celsius.
- Power requirements, 120/240 VAC; 50/60 HZ;
- The AccuSizer SIS Fluidics module and Counter need to be mounted on a horizontal workbench for optimum operation.
- The workbench must be able to support a minimum of 40 lbs. for the AccuSizer SIS Fluidics module with sensor and the AccuSizer Counter. The addition of the weight of the computer and accessories should also be taken into account.
- The workbench should be clear of sheets of paper or other objects which could block the flow of air to the fan mounted, internally, to the back of the AccuSizer Counter.
- Power sockets should not be obscured so that they can be disconnected in an emergency.
- Route all electrical cables away from areas where liquids can be spilt.

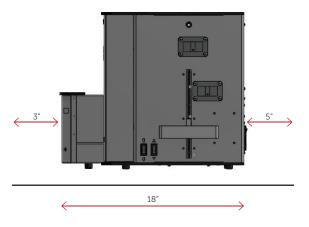
- Power sockets will be required for; the AccuSizer Counter, computer, printer and other accessories.
- The room must be well ventilated if noxious samples or dispersants are used.
- Space requirements are illustrated in the diagram below:



The space between the AccuSizer Counter and SIS Fluidics should be no less than 6" apart.



♠ WARNING: DO NOT STACK the AccuSizer APS Fluidics on top of the AccuSizer Counter.



Place the AccuSizer Counter to either the right or left side of the AccuSizer SIS Fluidics. The space between the AccuSizer Counter and SIS Fluidics should be no less than 6" apart.



▲ WARNING: DO NOT STACK the AccuSizer SIS Fluidics on top of the AccuSizer Counter.

## UNPACKING THE ACCUSIZER SIS FLUIDICS

Unpacking of the instrument is very straight forward. The tape must be removed from the top of the cardboard shipping carton exposing the second set of box flaps. Continue by lifting the second set of flaps open. The AccuSizer SIS Fluidics along with the documentation and accessories are nestled into the specialty formed foam inserts. The documentation and accessories can be removed and placed to the side.

Prior to lifting the AccuSizer SIS fluidics unit, ensure the workbench where the instrument is to be placed is clear.



WARNING: The AccuSizer SIS Fluidics unit weighs approximately 23 lbs. Assistance in lifting and positioning the instrument is strongly recommended.



A CAUTION: The AccuSizer SIS Fluidics unit may contain transit securing parts. These parts MUST be removed by a Entegris representative prior to powering up the unit. Damage will be caused if the transit securing parts are not removed.

## UNPACKING THE ACCUSIZER COUNTER

Unpacking of the AccuSizer Counter by first removing the tape from the top of the cardboard shipping carton exposing the second set of box flaps. Continue by lifting the second set of flaps open. The AccuSizer Counter along with the AccuSizer sensor and cables are nestled into the specialty formed foam inserts. The AccuSizer sensor and cables can be removed and placed to the side.

Prior to lifting the AccuSizer Counter, ensure the workbench where the instrument is to be placed is clear.



▲ WARNING: The AccuSizer Counter unit weighs approximately 18 lbs. Assistance in lifting and positioning the instrument is strongly recommended.

## LIFTING INSTRUCTIONS

Do not attempt to lift by bending forward. Bend your hips and knees to lower down to the item you are attempting to lift, extend your arms and place around item. Once the item is secure in your arms, keep it somewhat close to your body, and straighten your legs to lift. Never lift a heavy object above shoulder level. Avoid turning or twisting your body while lifting or holding a heavy object.

## **CARRYING INSTRUCTIONS**

Do not attempt to carry the AccuSizer SIS Fluidics module or AccuSizer Counter. If the instrument is to be moved use a cart where both modules can be placed on a clean, horizontal surface.

## SHIPPING CARTON STORAGE

Once the shipping cartons are emptied, they should be stored in the event that the instrument needs to be transported to a different location. Care should be taken when relocating the instrument as the transit securing parts will not be fitted. Relocation by commercial operators or international shippers is not recommended.

## **CHECK LIST OF ITEMS DELIVERED**

## **Major Components**

AccuSizer Counter Module (A7000) AccuSizer SIS Fluidics Module Sensor Module (LE400-05)

#### Cables

USB cable (computer controller)
Control port cable (14 Pin LEMO connector)
LE sensor cable – 10 Pin LEMO connector cable (for LE Sensor)
AccuSizer power cable

## Accessories Tubing, Stir Bars, and Syringes

Glass syringe(s)

Inlet tubing ( $\frac{1}{4}$  28 fitting or luer tip on one end) Sensor to syringe tubing ( $\frac{1}{4}$  28 fitting or luer tip on one end)

Drain tubing (1/4 28 fitting on one end) Extra tubing and fittings Stir bars

Fuses (Fuse 5A Slo Blo)

## **Test Standard**

Micro Measurement Lab Standard Certificate of Analysis

#### Software

AccuSizer System Software Controller
AccuSizer User Manual (Hard copy and/or digital)

## Sensor

Sensor Cleaning Kit including:

Floss

Micor-90 Certified Cleaning Solution

1-10 cc syringe

Calibration Curve for LE sensor (Hard copy and digital)

## Certificates

Certificate of Validation (Certificate to be completed by validator)

Certificate of Functional Performance (Certificate to be completed by a representative of Entegris.)

The AccuSizer SIS Fluidics, AccuSizer Counter, LE Sensor, documentation, accessories and cables have been carefully packed to avoid damage in transit, however, should any damage have occurred, contact your local Entegris representative immediately to inform them of any damage or shortages.

After checking that all the parts of the AccuSizer Syringe Injection Sampler (SIS) have been correctly delivered, the different units can be connected together. A Entegris representative will coordinate the installation of the instrument with the user initially. If in the instrument is to be relocated it is recommended that the Unpacking and installation section of this manual be used to correctly disconnect and reconnect all of the connections. Consult the manual provided with your PC for details on connecting the computer.

## ACCUSIZER COUNTER INSTALLATION

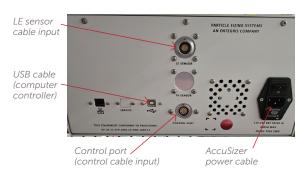
#### Material needed:

Flat-head screwdriver

- The AccuSizer Counter and AccuSizer SIS Fluidics modules should be placed immediately next to each other, along with the controlling computer, on a sturdy, level surface.
- Connect the 3 prong AC AccuSizer power cable to the AccuSizer Counter to the receptacle directly under the ON/OFF switch. Do not plug into power supply.



CAUTION: Before attaching the unit to AC power, the POWER ON/OFF switch must be OFF.



- 3. Connect the USB cable between the computer controller and the AccuSizer SIS Counter.
- 4. Insert one end of the controller cable (larger diameter gray LEMO cable) into the socket labeled Control Port on the back of the AccuSizer Counter. Line up the red dots and push in firmly until you feel a click.

- 5. Insert one end of the LE Sensor cable (smaller diameter gray LEMO cable) into the socket labeled LE Sensor on the back of the AccuSizer SIS Counter. Line up the red dots on the connector and the socket and push firmly.
- 6. Leave power OFF.

#### SENSOR MODULE INSTALLATION

#### Material needed:

Flat-head screwdriver

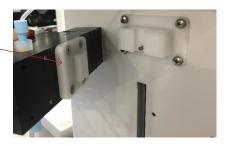
1. A white Delrin mounting bracket is attached to the AccuSizer SIS Fluidics module.



White Delrin mounting bracket attached to AccuSizer SIS Fluidics unit

2. If a white Delrin mounting bracket is not attached to the LE senor, using the 4 screws provided, attach the bracket using a Phillips head screw driver.

White Delrin mounting bracket attached to LE Sensor



3. Carefully slide the white Delrin bracket that is attached to the senor into the white Delrin mounting bracket that is attached to the AccuSizer SIS Fluidics.

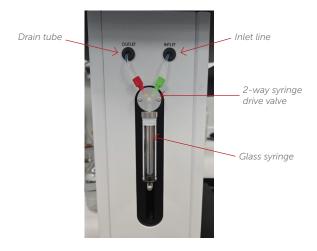


White Delrin mounting brackets joining LE Sensor to AccuSizer SIS Fluidics

- 4. Connect the free end of the LE sensor cable to the LE Sensor. Line up the red dots on the LEMO connector and push firmly until it clicks.
- Connect the free end of the Control cable to the AccuSizer Fluidics unit. Line up the red dots on the LEMO connector and push firmly until it clicks.
- 6. Apply power to the AccuSizer Counter.

## **FLUIDICS INSTALLATION**

Use the following steps to install the tubing and syringe onto the AccuSizer A7000 SIS Fluidics unit.



 Three pieces of Teflon tubing were supplied for the AccuSizer A7000 SIS Fluidics. All attachments should be hand tight only. Do not use any wrenches. Take caution not to cross thread fittings.

- 2. The syringe drive has two ¼ 28 threaded fittings located on the Teflon piece at the top of the syringe (2-way Syringe Valve). When facing the instrument the fitting located on the right side connects the top fitting on the LE Sensor (sample pull side).
- 3. The fitting located on the left side connects the syringe drive to the sample drain connector. Attach the waste tubing (this is the longest piece of tubing) which has one threaded end and one bare end to the ½ 28 fitting located on the left side of the syringe drive valve.
- 4. Place the bare end of the waste tube into a drain or waste container. Be sure that the waste container is lower than the fluidics unit to ensure proper flow.
- 5. The luer fitting located at bottom of the syringe drive connects the glass syringe to the Teflon™ valve assembly.
- 6. Install the 10 mL syringe by first wetting the plunger tip and inserting the plunger into the barrel.
- 7. Click Maintenance, Replace Syringe
- 8. Confirm that the Syringe drive arm is in the lowest position.
- 9. Thread the barrel tip into the syringe drive valve. Hand-tighten only.
- 10. Pull the plunger down manually until the end fits into the hole in the plunger arm. Hand-tighten the set screw

## SOFTWARE INSTALLATION

If a computer controller was purchased from Entegris, the software will already be installed. If however, the computer controller was not purchased insert the USB memory stick containing the software and run the AccuSizer Setup executable.

Place the computer controller next to the AccuSizer Counter

1. Confirm that the AccuSizer icon displays on the desktop.



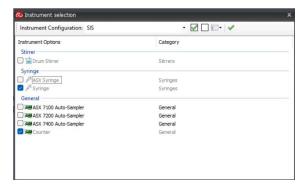
2. Log-in using the following information:

Username: admin Password: admin

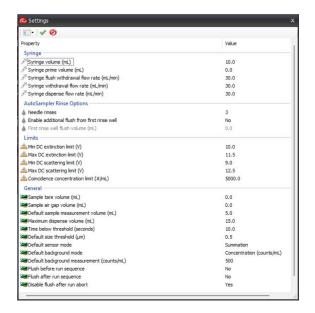


3. Click Instrument, Select Instrument, select SIS in the Instrument Configuration window, and click on the 

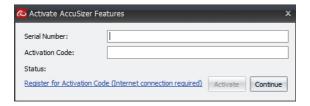
green check icon.



4. Click Instrument, Instrument Settings and enter the syringe volume being used. Other settings can be also be adjusted here. Click the green check icon.



 Click on the icon. The Activate AccuSizer Features window displays. The codes that are needed to enter into the following fields can be obtained by clicking on the http address provided.



6. The AccuSizer Activation Code Retrieval window displays. Complete all fields followed by clicking on Retrieve.



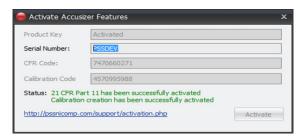
7. Once the form has been submitted, access your e-mail account and look for an e-mail from Entegris with the Subject line: Your AccuSizer 21 CFR part 11 activation codes. The contents of the e-mail will display. The codes shown in the above e-mail are only examples. These codes will not work if you enter them. You must generate your own.



8. Only the codes for your instrument configuration will be provided. If you did not purchase the 21 CFR Part 11 compliant software package or the Calibration option then these codes will not be provided. If you wish to purchase these packages, contact Entegris. Once the upgrades are purchased a new set of activation codes will be provided.



 Enter the Product Key code, Serial Number, CFR Code and Calibration Code and then click on Activate.



The status will change to:

21 CFR Part 11 has been successfully activated. Calibration creation has successfully activated.

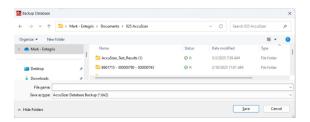
Calibration codes have a five day expiration period associated with them. They can only be generated by Entegris.

- 10. Close this window.
- 11. Once the codes are entered click on Activate.
  You will be asked to create a database backup file.



12. Continue by clicking on OK.

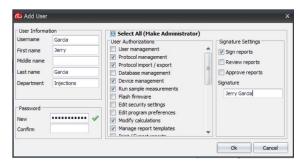
The backup database window displays prompting for a directory name of where the database backup is to be stored and then continues to prompt for a filename under which the data will be stored.



- 13. Once this information is entered, click on Save.
- 14. Access User Management from the Options pull down menu.



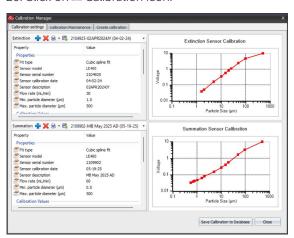
- 15. Select Add.
- 16. Create a new User Login ID assigning all permissions.



- 17. When finished, click on Ok.
- 18. Log out and re-login using the new username and password.
- 19. Be sure to keep track of the username and password.

During the installation of the software a prompt to install the Extinction and Summation calibration curves will display. If it did not display, follow these steps to install both calibrations:

20. Click on Calibration icon.



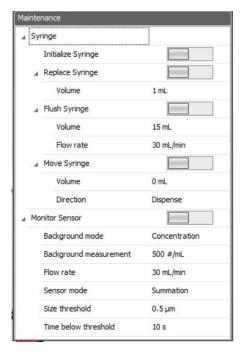
- 21. Click on displayed to the right of Extinction.

  From the window that displays, select the calibration file to be loaded. (Calibration File format: \*.sns)
- 22. Repeat prior step to load the Summation File.
- 23. Click on Close.

## **FLUSHING THE SYSTEM**

It is good practice to prepare the instrument for a sample run by flushing the chamber so that there is no chance that any residual from a previous sample run is left behind. Follow these steps to flush the instrument and review the count rates to ensure cleanliness of the system:

1. Click on the Maintenance icon or Maintenance tab.

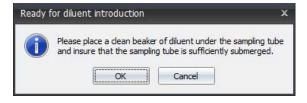


2. Locate Flush Syringe and enter the following parameters.

## Flush Syringe

Volume 10 mL Flow rate 30 mL/min

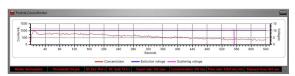
3. Slide the Flush switch to the right (On position). The prompt for diluent introduction displays:



- 4. If the Maintenance window does not reappear, click on the Maintenance icon or click on the Maintenance tab.
- 5. Locate Monitor Sensor section and enter the following parameters:

Background mode	Concentration
Background measurement	100 #/mL
Flow rate	30 mL/min
Sensor mode	Summation
Size threshold	0.5 μm
Time below threshold	1 s

- 6. Slide the Monitor Sensor switch to the right (On Position). The Particle Count Monitor window displays.
- 7. Observe the Count rate and Concentration located on the portion of the screen.



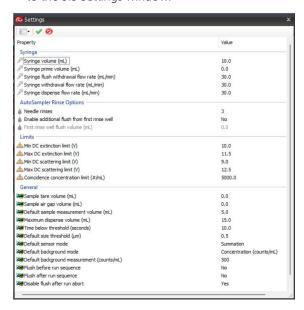
- 8. Once the Count rate falls to less than 50/sec and the Concentration falls below 100 counts/mL the instrument is ready for a sample run.
- 9. Click on the center of the main software window to Close when finished.

## **RUNNING A SAMPLE**

## INSTRUMENT SETTINGS AND DEFINING A PROTOCOL

Use the following steps to set the parameters for a sample measurement:

1. Select Instrument Settings from the Devices pull down menu or click on the 🗔 icon to gain access to the SIS Settings window.



2. Enter the following parameters:

## Syringe

Syringe volume (mL)	10.0  The syringe volume is dependent upon the size syringe that is installed.
Syringe prime volume (mL)	0.0
Syringe flush flow rate (mL/min)	30.0
Syringe withdrawal flow rate (mL/min)	30.0
Syringe dispense flow rate (mL/min)	30.0

Limits (see NOTE below.)			
Min DC extinction limit (V)			
Max DC extinction limit (V)	Max DC extinction limit (V)		
Min DC scattering limit (V)			
Max DC scattering limit (V)			
Coincidence concentration limit (	(#/mL)		
General			
Sample tare volume (mL)	2.0		
Sample air gap volume (mL)	0.0		
Default sample measurement volume (mL)	5.0		
Maximum dispense volume (mL)	10		
Time below threshold (seconds)	1		
Default size threshold (μm)	0.5		
Default sensor mode	Summation		
Default background mode	Concentration (counts/mL)		
Default background measurement (counts/mL)	500		
Flush before run sequence	Yes		
Flush after run sequence	Yes		
Disable flush after run abort	No		

NOTE: To obtain these limits, look at the label that is applied to the side of the sensor. Locate the Service Code. The first three digits indicate the scattering voltage. The second three digits indicates the extinction voltage and the last four digits indicates the month and year that the sensor was manufactured.

#### Example:

## LE Sensor

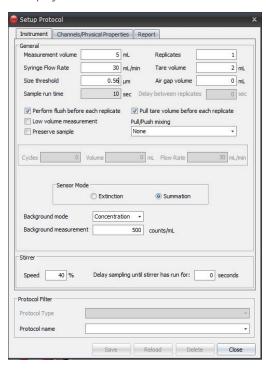
Service Code: 115-107-0317

115 indicates that the scattering voltage for this sensor is 11.5 107 indicates that extinction voltage for this sensor is 10.1 0317 indicates that the sensor was manufactured in March of 2017

#### Calculate Min/Max:

Remember these are the recommended tolerances for the sensor. To calculate the Min/Max for the extinction sensor,  $\pm$  0.5 volts. To calculate the Min/Max for the scattering sensor,  $\pm$  0.8 volts. The coincidence concentration limit is set to 3500-4000 particles/mL.

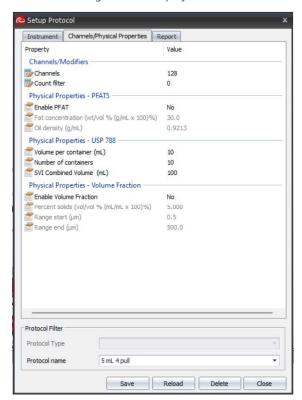
- 3. Click on **✓** icon.
- 4. Select Protocol from the Sample pull down menu or click on the Sicon.
- 5. Click on the Protocol tab. The following window displays:



6. Click on the Instrument tab and enter the following parameters:

Instrument	
Measurement volume	5 mL
Replicates	4
Syringe Flow Rate	30 mL/min
Tare volume	1 mL
Size threshold	0.56 µm
	This is dependent on the sensor lower limit.
Air gap volume	0 mL
Sample run time	10 sec
	This field is grayed out since the run time is predetermined by the flow rate and measurement volume that was previously entered.
Perform flush before each replicate	Select
Delay between replicates	<grayed out=""></grayed>
Preserve sample	Do not select.
Pull tare volume before each replicate	Do not select.
Pull/Push mixing before each replicate	This option is used for samples with fast settling particles.
Sensor Mode	Summation
Background mode	Concentration
Background measurement	500 counts/mL
Stirrer	
Speed	40%
Delay sampling until stirrer has run for	0 seconds
Protocol	
Protocol name	<user defined=""></user>

- 7. Click on Save and enter the Protocol name for which these parameters are to be saved.
- 8. Click on Channels/Physical Properties tab and the following window displays:



- 9. Select 128 for the number of channels from the pull down menu and leave the Baseline offset field set to 0.
- 10. Skip the Physical Properties for PFAT5, USP788 and General. Please refer to the Data Calculations section of this manual for the required steps in making these calculations.

11. Select the Report tab. The following will display.



12. Click on Auto Run Reports.

## 13. Enter the following options:

Report Option		
Channel Table	Yes	
Cumulative	Descending	
Diameter	As a range	
Show channels below threshold	No	
Show Counts as	Counts	
Distribution Values		
D#'s (10, 50, 90)	No	
Max diameter size		

## General

Graph	Counts/mL v. Size
PFAT5	No
Signature Approvals	No
Statistics	No
Volume Fraction	No

- 14. Select the Protocol name with the variables to be applied to this sample run.
- 15. Click on Save. The report will automatically be generated when this protocol is used.

## **SAMPLE PREPARATION**

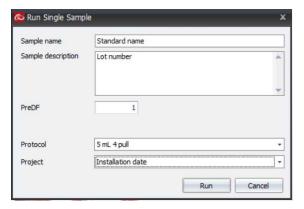
Perform a particle size measurement using the standard provided by Entegris to establish how a sample can be run, results saved, printed and/or exported correctly.

- 1. Mix solution of reference latex material by inverting the bottle approximately 10 times.
- 2. Fill a particle free 1 liter beaker with 500 ml of filtered distilled water.

- 3. Using the precision pipet, add 200 microliters of the standard into the 500 ml of filtered distilled water.
- 4. Mix dilution.

## **MAKING A MEASUREMENT**

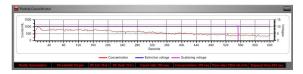
1. Click on the licon to start the sample run.



2. Enter the following information:

Sample name	Enter the name that the sample data is to be saved.
Sample description	Enter a brief description for the sample run.
Protocol	Enter the name of the protocol that has the parameters by which the sample is to be run.
Project	Enter the project name under which the sample name (run) is to be saved.

- 3. Once the information is entered, click on Run to start the sample run.
- 4. The Particle Count Monitor Window displays.



To view the sample analysis, position the cursor in the lower half of the window and click on the graphic window. Drag the window up to the top half of the window. Running count and rate voltages display. Once the analysis is complete the window will leave the display.

## DATA INTERPRETATION

- 1. In the Sample explorer panel on the left side of the software screen, click on the Project name for the data just taken and a list of dates for when the sample runs were made displays.
- 2. Click on the date is icon next to the date that measurements were made. A list of Run names displays. Locate the run name for this sample run.
- 3. Click on the run name followed by clicking on the icon to gain access to the particle size distribution for the sample run. The particle size distribution graph (counts vs particle size) appears in the area to the right of the window.
- 4. Click on Reports and a list of reports that was defined in the Protocol will display under the report icon and to the right side of the window.
- 5. Click on the report to be viewed and/or printed under the report icon on the left side of the window. The report will display in the right window. Clicking on the report name on the right side of the window will not display the report.
- 6. Click on the desired report format followed by clicking on the 🖳 icon to print. Follow the prompts for the printed setup to the system computer.



7. To print only the graphical representation of the sample run, right click on the graph. Access to data options displays as follows:



- 8. Select units and continue to select the format in which the data is to be printed or saved.
- 9. To print, select Print and then Plot. Follow the prompts for the printer hooked up to the computer.

10. Right click on the graph and select Data followed by selecting Export. The data can be saved in Excel format.

## INSTRUMENT FEATURES

Using the instructions of the previous sections, the system is now connected. Take some time to familiarize with the features of the instrument.

This section provides a guide to identify the features of the system. A description of the theory of operation of the system is given in the AccuSizer Theory Manual (Part Number 998-001). An AccuSizer User Manual, that accompanies the instrument, provides a description of the software (Part Number 998-002). The AccuSizer User Manual is also accessible from the AccuSizer Software.

All AccuSizer systems consist of a sensor, pulse height analyzer (counter), and fluidics to transport the sample through the sensor. A computer is used to run the AccuSizer software that analyzes the raw data to provide the results as particles flowing through the sensor they scatter and obscure the incident laser beam. This light interaction creates pulses that are proportion to the size of the particle. The counter converts these pulses to particle size and counts.

## SENSOR

The LE Sensor features a collimated beam of light and two detectors for scattered and obscurated light to determine particle sizes over the range of 0.5-400  $\mu m$ .



## ACCUSIZER SYRINGE INJECTION SAMPLER (SIS) INSTRUMENT

The AccuSizer SIS is used for low concentration samples that do not require any or little dilution. Volumes down to 150  $\mu$ L are drawn through the sensor and the sample is conserved for other analyses.

The diagram below shows a typical system with the AccuSizer SIS Fluidics and AccuSizer Counter.



A computer is used to run the AccuSizer software that analyzes the raw data to provide the results.

## ACCUSIZER COUNTER (A7000 - CTR)

The AccuSizer Counter (pulse height analyzer) contains the electronics that control the AccuSizer SIS fluidics and collects the raw data in 1024 size channels.

## **ACCUSIZER SIS FLUIDICS**

The AccuSizer SIS Fluidics unit is used to transport sample through the LE Sensor either with our without dilution and then analyze the sample using the LE Sensor that is mounted inside of the unit.

## **MAINTENANCE PROCEDURES**

## **ACCUSIZER SIS PREVENTATIVE MAINTENANCE**

The main parts of the instrument that require routine maintenance are the AccuSizer SIS syringe and tubing and LE sensor calibration.

## **DAILY MAINTENANCE**

Preventive maintenance for the AccuSizer SIS can and should be performed on a daily basis.

- Always flush the system adequately to achieve the same background counts (#/ml) as was present before the particle size analysis.
- The external tubing should be visually checked for deterioration and signs of wear. If any parts of the tubing are cracked or show signs of excessive wear they should be replaced.
- The syringe and drive should be checked for cracks and/or deterioration. The key is to make sure that the syringe is moving freely in both the flush and analysis mode.

NOTE: In some cases the syringe will look fine in the flush mode where the syringe is traveling at a high rate of speed but may hang up and shutter in the sample analysis mode where the lower flow rates mean that the syringe will move at a slower rate.

 The Summation Voltage as reported in the Sensor Status Screen should read >10 Volts.

## **MONTHLY MAINTENANCE**

The sensor calibration should be checked once every month with a single point standard reference material that is used in the calibration of the system.

## YEARLY MAINTENANCE

The sensor should be re-calibrated once every year depending on operating conditions according to the sensor calibration procedure outlined in the, Accu-Sizer SIS Calibration using AccuSizer Software (Part Number 992-019). Calibration of a sensor can also be performed for a fee by a Entegris Representative.

## **SENSOR CALIBRATION**

The accuracy of the AccuSizer SIS instrument is dependent on the correct calibration of the sensor installed. A yearly calibration is recommended and should be carried out in accordance with the document entitled, AccuSizer SIS Calibration using AccuSizer Software, Manual Part Number 992-019.

The following procedures are performed:

- Cleaning of Sensor and System Flushing
- Sensor Calibration Procedure Summation Mode
- Sensor Calibration Procedure Extinction Mode
- Calibration Verification

## REPLACING FUSES

Periodically the fuses found in the power socket of the AccuSizer Counter will need to be replaced. Use the following steps for successful replacement:

## Materials needed:

Flat-head screwdriver

1. Ensure that the power is set to the off (0) position on the AccuSizer Counter.



2. Disconnect the counter from the power source and unplug power cable from power socket located on the back of the counter.



3. Position the flat head screwdriver at the top of the fuse box.



- 4. Gently pitch the screwdriver inward and then out to release the fuse box.
- 5. Slide the fuse box out. One fuse is located on each side of the fuse box.





6. Replace each fuse with a new one. New fuses are included in the accessories pouch packed with the instrument.

7. Once both fuses are replaced, slide the fuse box into the power socket until the outer cover is mesh with the rest of the socket. Take note of the direction in which the fuse box is replaced. If the AccuSizer Counter is working with 110-120 volts be sure to flip the fuse holder so that the arrow located below the 110-120V label aligns with the arrow on the frame of the fuse holder. If the AccuSizer Counter is working with 110-120 volts be sure to flip the fuse holder so that the arrow located below the 220-240V label aligns with the arrow on the frame of the fuse holder.



8. Plug/Unplug power cable from power socket located on the back of the counter and connect to power source.



#### SENSOR CLEANING

## Materials included in Sensor Cleaning kit:

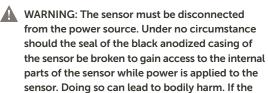
Micro 90® Certified Cleaning Solution Clean Super floss 30 mL bottle - empty 10 cc syringe

## Materials needed:

1 can pressurized air

NOTE: Do not replace floss with waxed dental flow. This will lead to the coating of the cell wall of the sensor.

- 1. Drain all tubing leading to the LE Sensor.
- 2. Exit the AccuSizer software.
- 3. Power down the instrument which includes the computer and the AccuSizer Counter.



seal is broken, the warranty is null and void.

4. Carefully slide the white Delrin bracket that is attached to the senor up to release the LE sensor from the side of the AccuSizer SIS Fluidics.



White Delrin mounting brackets joining LE Sensor to AccuSizer SIS Fluidics

- 5. Unscrew both the intake and outtake tubing from the LE Sensor.
- 6. Disconnect the free end of the LE Sensor cable (LEMO connector) to the LE Sensor.
- 7. The sensor is now free.



MARNING: Breaking the seal of the sensor while power is applied, will expose the sensor classifying it as Class 3B. Exposure can lead to bodily damage. If the seal is broken, the warranty is null and void.

8. Using the can a pressurized clean air, back flush the sensor by spraying from the bottom of the sensor up. This will dislodge any particles that may be clogging the sensor.

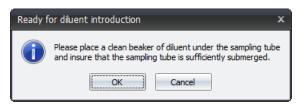
NOTE: Do not use common house air. It contains oil contaminants that can coat the sensor windows.

- 9. Pour a small amount of Micro 90® into the empty bottle supplied. Store the remainder.
- 10. Thread the long, white end of a single strand of the cleaning floss provided into the orifice of the sensor until the thick part of the floss is in contact with the connector.
- 11. Using the Micro 90® provided soak the thick, fuzzy part of the floss.
- 12. Gently pull the thick end of the floss back and forth four or five times through the sensor scrub all four sides of the sensor flow channel.
- 13. Remove the floss from the sensor without pulling the blue end through the sensor.
- 14. Flush the sensor using a clean 10 cc syringe and particle free distilled water.
- 15. Back flush the sensor by spraying pressurized air from the bottom of the sensor up.
- 16. Through visual inspection, hold the sensor up to the light to see if the optical path is free of any blockage.
- 17. The sensor is now clean.
- 18. Screw both the intake and outtake tubing back into the sensor.
- 19. Carefully slide the white Delrin bracket that is attached to the senor into the white Delrin mounting bracket that is attached to the AccuSizer SIS Fluidics.



White Delrin mounting brackets joining LE Sensor to AccuSizer SIS Fluidics

- 20. Connect the free end of the LE Sensor cable to the LE Sensor. Line up the red dots on the LEMO connector and push firmly until it clicks onto the sensor
- 21. Power up the instrument which includes the computer and the AccuSizer Counter.
- 22. Access the AccuSizer software.
- 23. Locate the Maintenance window and slide the Monitor Sensor button to the right to activate.
- 24. Follow the prompts from the software and click on OK.



- 25. Be sure that fresh diluent is being introduced into the AccuSizer SIS Fluidics.
- 26. Observe the count rate. This is indicative that there is flow through the sensor confirming that it is no longer blocked or dirty.

## **STORAGE**

If the system will be stored for a long period of time use an aqueous, sterilizing agent and water mixture to keep all of the major sensor components wet.

## TROUBLESHOOTING

## **DRY SENSOR**

Do not allow the sensor to run dry. The residue from the sample will build up a film on the cell of the sensor that will affect the baseline noise level and particle sizing capabilities of the sensor.

## **CLEAN BASELINE**

Always flush the system after every run and make sure that it returns to a clean baseline. Leaving chemicals in the cell can damage the optical path.

## **SOLVENT COMPATIBILITY**

Whenever using a solvent always check to make sure it is compatible with all of the tubing and components inside the system. If any doubt exists concerning how the solvent will affect the tubing check by submerging a small piece of tubing in the solvent and monitoring its physical properties. Please also check Appendix B: Filter and Tubing Compatibility of the AccuSizer User Manual (Part Number 998-002).

After using a solvent always clean and flush the system with proper materials to return to a water based system.

## **DILUENT GRADE**

Always try to use cleanest grades of diluents available when performing particle size analysis. There is no concrete number when it comes to background counts but if the maximum count rate of the sensor is 10,000 particles per mL and the background is hovering around 1000 counts per ml then your signal to noise ratio is 10 to 1 or 10%. This may be fine for some applications but if the analysis calls for identifying small amounts of material on the tail of a distribution this background level will not be acceptable. It is always true that cleaner is better but one has to weigh the benefits versus the time needed to further clean the diluent when making an analysis. In most cases backgrounds below 100 particles per mL are acceptable.



CAUTION: Standard equipment supplied is not rated for Organic solutions. Call the manufacturer if you are in doubt.

#### NO COUNTS

No signal in the Monitor Sensor window. By clicking on Monitor Sensor, the sensor health can be determined by looking at Sensor Voltages and viewing the electronic pulses that are being generated by the sensor.

#### Remedies:

- Make sure that the sensor cable is plugged into the AccuSizer Counter and the LE sensor, and that the serial cable between the counter and the computer is in place with a good connection.
- Make sure that the instrument is monitoring the correct serial port.

## HIGH BACKGROUND COUNTS

System background does not come down. This is usually an indication that the system's tubing and sensor are dirty OR the glassware used to introduce the diluent is dirty.



CAUTION: Particle Sizing System accepts no liability in case of sensor damage during cleaning.

## Possible Causes:

- Sensor tubing is dirty
- · Sensor is dirty
- Aerated Diluent
- Air in the Fluidics

## Remedies:

- Flush the system with a solution of 5% micro cleaner in water.
- Removal of the sensor may be required to clean the optical path. This is not a difficult task, however care must be taken to prevent against dropping the sensor. Particle Sizing System accepts no liability in case of sensor damage during cleaning.

- · Remove and clean or replace the tubing.
- Let diluent sit over night before using it to allow small air bubbles to percolate out.
- Examine all tubing for bubbles. One can remove bubbles by tapping on the tubing while the system is flushing to release the bubbles from the sides of the tubing.

## **INSTRUMENT VOLTAGE**

There is a flat black line across the screen at either 1 or 10 volts when using the Monitor Sensor and viewing the Instrument Voltage. This is usually an indication that the sensor is blocked by something and that the signal is not reaching baseline. This can be a partial block that even may allow fluid to flow through the sensor.

## Remedy:

 Remove and clean the sensor as well as all of the tubing before the sensor in the instrument flow path. Refer to the Sensor Cleaning section of this manual.

## SENSOR VOLTAGES ARE TOO LOW

#### Possible Causes:

- · Sensor is not connected to counter.
- AccuSizer Fluidics may be dirty.
- Air is trapped in sensor.
- · Sensor is dirty.

## Remedies:

- Check electrical connection between the AccuSizer Counter and sensor.
- Flush system repeatedly.
- Start a flush and tap the tubing above and below the sensor to release air bubbles.

## SENSOR VOLTAGES ARE TOO HIGH

#### Possible Cause:

Sensor dirty.

## Remedy:

 Clean Sensor – Refer to the Sensor Removal and Cleaning section of this manual. If still high, i.e. >12.5V, Call Entegris.

## **BUBBLES IN DILUENT**

There are air bubbles in the diluent (water supply). In some water filtration systems the water is pressurized through various stages of filters and during this process air is pressurized into the water. When the aerated water is placed in the glassware the pressure is reduced and the air starts to degas out of the liquid. This causes the instrument to count the air bubbles as though they are particles that can have a major effect on the particle size distribution.

#### Remedies:

- Sonicate and heat the liquid to de-gas.
- Draw a vacuum on the liquid to de-gas.
- Allow the diluent to sit for several hours before use will often remedy the situation.

## APPENDIX A: CHEMICAL COMPATIBILITY

The identification of chemicals and the sensor configurations required for operation.

CHEMICAL	GLASS
Acetone	Compatible
Ammonium Hydroxide	Compatible
BOE (Buffered Oxide Etch)	Compatible
Developers	Compatible
Dimethyl Formamide	Compatible
Ethylene Glycol Monethyl Ether Acetate	Compatible
H <sub>3</sub> PO <sub>4</sub> /HNO <sub>3</sub> /Acetic Acid	Compatible
Hydrochloric Acid (<37% concentration)	Compatible (Liquid)
Hydrofluoric Acid	
Hydrogen Peroxide	Compatible
Isopropyl Alcohol (IPA)	Compatible
n-Butyl Acetate	Compatible
n-mothyl Pyrilidone (NMP)	Compatible
Nitric Acid	Compatible
Phosphoric Acid	Compatible (All temps.)
Potassium Hydroxide	Compatible
Propyl Glycol Monethyl Ether Acetate	Compatible
Sodium Hydroxide	Compatible
Sulfuric Acid	Compatible
Tetramethylammonium Hydroxide	Compatible
Xylene	Compatible

If questions arise concerning the chemical compatibility of a chemical or a chemical blend, contact Entegris prior to performing sample analysis.

## **APPENDIX B: TECHNICAL SPECIFICATIONS**

## **ACCUSIZER SPECIFICATIONS**

Specifications	AccuSizer SIS Instrument	
Samples/applications	Water, Injectables, Clean Chemicals	
Sensors	LE400-05; 0.5-400 $\mu$ m, light extinction and scattering, summation calibration, particle sensitivity to 10 PPT, concentration limit ~ 9000 particles/mL, size accuracy 2%, count accuracy 15%, recommended flow rate = 30 mL/min, but can be calibrated at other flow rates depending on configuration.	
	Physical Size: $6.5$ "w $\times$ $2$ %"d $\times$ 2"h, $1.6$ lbs	
Wet or dry	Aqueous or Organic	
Dimensions	AccuSizer Counter: $12"w \times 18"d \times 7"h$ , $18.6$ lbs	
	AccuSizer SIS Fluidics: $10"w \times 18"d \times 22"h$	
Wetted surfaces	Glass, Teflon, Kel-F, Viton (optional Kelrez replacement)	
Syringe sizes	0.5, 1,2.5, 5, 10, and 25 ml syringes	
Requirements	Waste reservoir	
Software options	AccuSizer software	
	AccuSizer 21 CFR Part 11 compliant software	
Computer requirements	Basic computer or laptop with USB port. Windows 7 operating system or better. Suggested 4 GB of RAM and 200 GB hard drive storage.	

## APPENDIX C: STATEMENT OF EMC PERFORMANCE STATEMENT OF LVD COMPLIANCE

## **EMC PERFORMANCE**

A system comprising of the AccuSizer Syringe Injection Sampler (SIS), AccuSizer LE Sensor, AccuSizer Counter and computer was tested against and found to be compliant with the EMC standard:

BS EN 61326:1998, IEC 61326:1997 – "Electrical equipment for measurement, control and laboratory use – EMC requirements".

## STATEMENT OF LVD COMPLIANCE

The CE-badge on these products signifies conformance to European Commission Directive

73/23/EEC the Low Voltage Directive as amended by Directive 93/68/EEC, the CE Marking

Directive. This directive has been satisfied for Entegris equipment by applying:

BS EN 61010-1:1993. – "Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1 – General requirements." with the incorporation of amendment A2:1995.

## LIMITED WARRANTY

Entegris' products are subject to the Entegris, Inc. General Limited Warranty. To view and print this information, visit <a href="mailto:entegris.com">entegris.com</a> and select the <a href="Legal & Trademark Notices">Legal & Trademark Notices</a> link in the footer. Entegris does not warrant any failure in the case of customers using unapproved foreign components.

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Corporate Headquarters 129 Concord Road Billerica, MA 01821 Customer Service

Tel +1 952 556 4181

Fax +1 952 556 8022

Toll Free 800 394 4083

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Field Service Manual 998-006-08 www.entegris.com