SOFTWARE UPDATE NOTIFICATION (SUN) – ZETASIZER SERIES OF INSTRUMENTS SOFTWARE: PSS0012-36

PARTICLE SIZE

RHEOLOGICAL PROPERTIES

MOLECULAR WEIGHT

ZETA POTENTIAL

Introduction

This document details the release of software PSS0012-36. This is the Zetasizer software version 7.10.

It covers the additions and improvements as well as issues fixed in this release of the software.

Note: If you are upgrading from any version before 7.01, you should also read the SUN documents issued with version 7.01, 7.02, 7.03 and 7.04.

Installation

It is assumed that you have authority to install or update software within your company's SOPs. If you do not have this authority please consult with your I.T. support department before proceeding.

It is assumed that you have Administrator rights for the computer. This is required by the installation process. For Zetasizer Series software, Windows 7 and later will not allow an installation if the user does not have administrator access. This is in line with Microsoft's Logo policy and is standard practice.

Before installation of the software, the instrument must be switched off and disconnected from the USB connector of the PC.

Recommended System Requirements

Intel Core 2 Duo, 4GB RAM, 160GByte hard disk drive, 1024 x 768 screen resolution running in 32 bit colour mode, CD-ROM drive, 1 free USB port, Windows 7 operating system.

Supported Languages

- English
- Japanese

Supported Operating Systems

The following operating systems are supported by the Zetasizer software v7.10:

- Windows 8 (32 bit and 64 bit)
- Windows 7 (32 bit and 64 bit)
- Windows XP 32 bit (SP3 or higher)

Supported Software Integration

If using existing Zetasizer software with any of the following it is **not recommended** to upgrade to v7.10:

- Malvern Link II
- Any 3rd Party Software
- CONTIN analysis

Installation Instructions

The software suite comes on an auto-loading CD-ROM. Inserting the CD into a system configured to auto-run a CD will run the installation program automatically. If your system does not support this feature run the setup program from the root directory of your CD drive.

Note: All DTS version 3.xx, 4.xx, 5.xx, 6.xx software must be uninstalled before version 7.10 is installed. The installer will uninstall a previous version if it detects an older version is installed (7.xx and later only).

During the installation process, if the installer detects that an instrument is connected, you will be prompted with the following message (Figure 1).
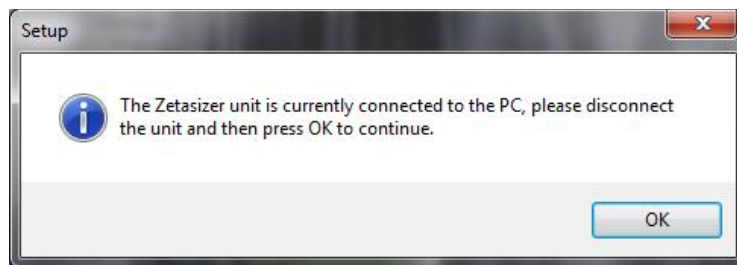

Figure 1: "Disconnect Zetasizer Unit" message

You must unplug the USB cable from the PC or Zetasizer Nano and then press OK. If you press the OK button without performing these previous steps then the installation will not continue.

### Microsoft .Net Framework 4

The Microsoft .Net Framework 4 must be installed for the Zetasizer software to run. This is installed during the Zetasizer software installation progress and under certain circumstances can involve the PC needing to restart. Completion of this stage of the installation can take a few minutes, and in the case of Windows 7 64 bit can take over 10 minutes. Whilst the .Net Framework is being installed the following window will be displayed:
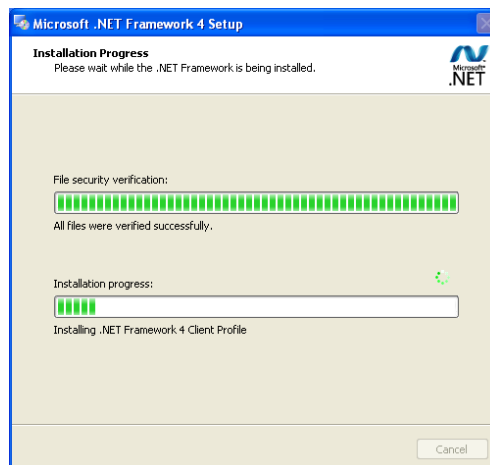
Figure 2: Microsoft .Net 4 Installation Window

Running the installer before the Zetasizer Software has closed down

If the installer is run immediately after closing down a previous installation of the Zetasizer Software then the error shown in Figure 3 may be displayed during the installation process.
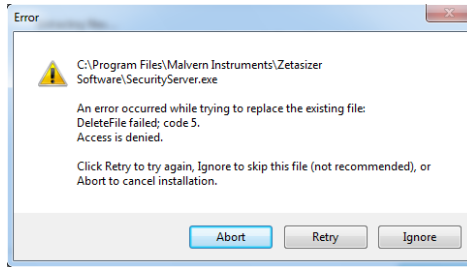
Figure 3: Warning during installation

If this error is encountered then the user must open Windows Task Manager, go to the Processes tab and select the process described in the first line of the warning (in Figure 3 this would be "SecurityServer.exe") and then select "End Process". Once this is done the Retry button can be selected on the original error window and the installation will continue successfully.

USB Driver Installation

During the installation of the USB drivers you may be prompted twice with the message shown in Figure 4.
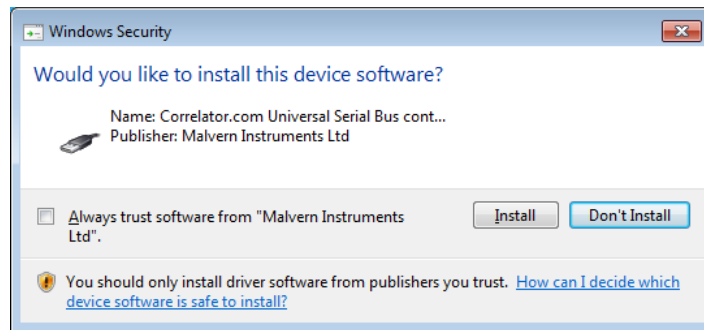
Figure 4: Install USB window

This warning can safely be ignored as the software installation has been fully tested on Windows 7. Press "Install" to continue installation of the USB drivers.

Installation with Viscotek OmniSEC software

If the Zetasizer software is being installed on a PC that already contains the Viscotek software OmniSEC version 4.7, the following message may appear:
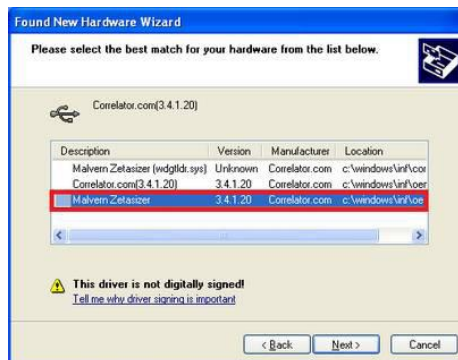
Figure 5: Select USB Drivers on Windows with OmniSEC software

Select the 'Malvern Zetasizer' and click 'Next'. The '**Malvern Zetasizer (wdgtldr.sys)**' option must not be selected.

Connecting the Zetasizer to the PC

When the software has been installed and the instrument has been connected via the USB port, and switched on, Windows may display the New Hardware Wizard window (Figure 6).

Figure 6: New Hardware Found Wizard

The first page asks for permission from the user to search for updates on Windows Update. Select "No, not this time" and then press Next and the following window will then appear:

Figure 7: New Hardware Wizard Installation Page

If you are connecting to a Zetasizer APS or Zetasizer μV, the name used to identify the hardware will be displayed as "Malvern Zetasizer" rather than "Malvern Instruments Nano".

This window should be left with the default selection of 'Install the software automatically' and the 'Next' button should be selected so that file transfer begins. Once file transfer has completed the 'Finish' button should be selected to complete the installation. At this point Windows will indicate that the new hardware is installed and ready to use.

You may see the same security warning as shown in Figure 4. The warning can safely be ignored as the software installation has been tested on Windows 7 and Windows XP. If the warning is encountered the Install button should be pressed.

In Windows 7, when the Zetasizer Nano is installed, it is possible that the message 'Device driver software was not successfully installed' will be displayed in the bottom right-hand corner of the screen (Figure 8).
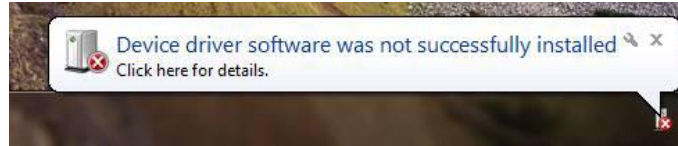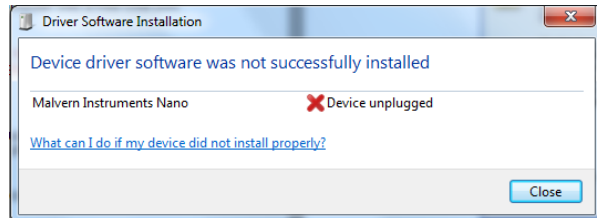

Figure 8: Device Driver not successfully installed

Alternatively, the following message may appear.

These messages can be safely ignored as long as, when the Zetasizer software is started, the 'Nano' icon is enabled (Figure 9).
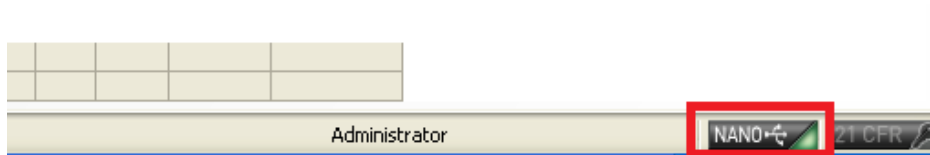

Figure 9: Nano Connected Icon

Zetasizer APS and µV users

Due to a driver update in the 7.02 release of the software, you may have to follow the steps described above to install the driver twice. This should only occur with new APS and µV instruments on Windows XP.

Running the software

When the software is started the first time, the following dialog box will appear. Click on the appropriate system to select it. This dialog will not appear the next time the software is started.
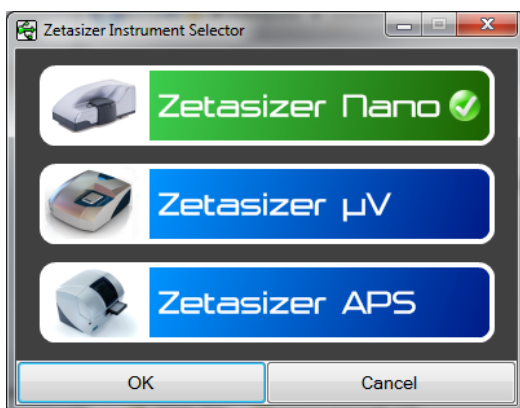
Figure 10: Zetasizer Instrument Selection

The instrument type can be changed at any point by selecting the menu item; 'Tools', 'Options', 'Instrument type'. Once the instrument type has been changed the software must be restarted for the change to take effect.

Uninstall Procedure

The software can be uninstalled using the standard Add/Remove feature in the Windows Control Panel'.

New Features

Feature	Comment
Autosampler Functionality	New Feature
Bug fixes from 7.04	Improvement

New Features Description

The Zetasizer NanoSampler is a versatile, compact sample management autosampler that makes highly precise and reproducible injections of samples into your Zetasizer Nano. This release of software facilitates the control of the Nanosampler through the use of the SOP Player controls.

Figure 11 The Zetasizer Nano with a Nanosampler

GAMP 5 Software Categorization

The GAMP 5 guide provides guidance to pharmaceutical companies wishing to understand whether the computerized systems and software they used are fit for purpose and meet current regulatory requirements. As part of this, the GAMP committee have defined a series of software categories which are designed to help users in assessing the risk and validation requirements associated with using a specific software package.

The Zetasizer software provides users with the ability to modify the results reported by the system to fit their specific application requirements. This is achieved through the use of custom calculations within reports and also through the application of emulation factors as part of the analysis settings . Given this, the software should be considered to be a Category 5 software package. Users are therefore encouraged to specifically validate the custom calculations and emulation factors applied within SOPs, and ensure these are documented. Where possible, we would encourage the use of the standard result reporting features, as this minimizes the risk of errors in the reported size distribution statistics.

Fixed issues

Reference(s)	Issue	Comment
33365	Update the APS SLS macro header to include version, description and copyright information	Fixed
14133	Laser turns off during long trend measurements in the green laser variant of the Nano ZS	Fixed
30931	Error messages displayed when accessing the Microrheology report page when there is no data in the results file	Fixed
32327	Installation macros failing on Windows 8	Fixed

Known Issues

The following software bugs have been discovered within the software, and will be investigated as part of a future release. Please follow the suggested work-around for

Issue	Work around	Comment
Using CONTIN analysis (in Research mode) can cause the NanoSampler schedule to fail	If CONTIN analysis required, create SOP with general analysis and reanalyze data using CONTIN.	Software Bug
New workspaces have been created to support the new measurement types. However, due to the way the software is updated, they will not appear if a current Zetasizer user is having their software upgraded.	In order to install the new workspaces, the user should select 'import workspace' from the tools – settings – configure workspace menu, browse to the location of the workspace they are interested in, (located in C:\Program files\Malvern Instruments\Zetasizer\Export Data) select it and then press "OK".	Software Bug
Some PCs, running the Zetasizer software, may lock-up or freeze when connected to an APS or µV.	The APS and µV both require a PC with at least two cores or alternatively, a CPU that is Hyper-threading (HT) enabled. Therefore, it is advisable to run the software on a PC that meets the recommended specification detailed earlier in	Hardware requirement

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	this document if the PC is to be connected to either a Zetasizer APS or Zetasizer µV. The Zetasizer Nano is not affected by this issue.	
USB detection occurs automatically on new computers. On older computers the instrument is not always detected automatically and the instrument icon in the bottom right-hand corner of the status bar will remain greyed-out	This is fixed by closing the application, restarting the computer and restarting the software.	Hardware
The parameter dictionary has been updated in version 7 of the software and some of the parameters have changed. For reports that the user may have created containing the affected parameters, the parameters will become undefined.	This can be seen when a report is opened and the parameter displays the text 'No parameter has been selected' or if the nothing is shown next to the text label (i.e. the value appears blank). To fix this problem for each parameter carry out the following steps:- 1) Double-click on the affected parameter to bring up its property dialogue. 2) Click the 'Select' button to display the 'Select a parameter' dialogue. 3) Select the relevant parameter. **N.B. Remember to correct the affected parameters on both the screen and page layout views**	Software Update
SOP sample settings can be lost on software upgrade	The SOP sample settings will be copied to a backup location during the installation process. To maintain these settings with the new installation, the following process should be followed: Once the files have been backed up and the new software installed, to incorporate these settings, the relevant files need to be manually copied by the user to the correct location to replace the installed files. To do this the following steps need to be followed: 1. Ensure that you are logged onto the computer as an administrative user 2. Run the Zetasizer software once then close it down so there are no copies of it running. 3. Use Windows Explorer to copy the files: SampleProperties.cfg CompoundProperties.cfg IonicSpecies.cfg to the relevant location. The locations of the files depend on the operating system:	Software Update

	Windows XP Copy from C:\Documents and Settings\All Users\Application Data\Malvern Instruments\Zetasizer<date/time of install> to overwrite files in C:\Documents and Settings\All Users\Application Data\Malvern Instruments\Zetasizer Windows 7/8 Copy from C:\ProgramData\Malvern Instruments\Zetasizer<date/time of install> to overwrite files in C:\ProgramData\Malvern Instruments\Zetasizer N.B. The Application Data folder is a hidden folder. To view it on Windows XP you need to access the Control Panel then select Folder options->View and then enable the option to Show hidden files and folders. N.B. The ProgramData folder is a hidden folder. To view it on Windows 7 you need to access the Control Panel then select Appearance and Personalization->Folder Options->Show Hidden files and folders and then enable the option to Show hidden files, folders and drives. N.B. If the installation process is terminated prematurely, the backup from the last installation is maintained in the following directory: Windows XP - C:\Documents and Settings\All Users\Application Data\Malvern Instruments\Zetasizer_BACKUP Windows 7 - C:\ProgramData\Malvern Instruments\Zetasizer_BACKUP	
PC entering sleep mode can disconnect the Zetasizer	It is recommended to disable the sleep function while the Zetasizer is being used.	Software Bug
If, during a measurement, the lid is opened, all of the safety cut offs will work as expected, but the measurement will continue to completion rather than aborting.	No workaround available as instrument operation is not affected.	Software Bug
Occasionally, it has been observed that feature keys can be disabled after detaching one instrument and then attaching a different instrument.	This problem can be resolved by restarting the Zetasizer software.	Software Bug
The 21CFR audit trail does not update if the Windows user is changed from the original user that installed the 21-CFR key. This is the case in both Windows 7 and	The following procedure should be followed to enable the 21CFR Part 11 ER/ES audit trail for all users: 1. Open Windows Explorer as an administrator	Software Bug

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Windows XP.	to edit the file permissions. 2. Windows 7/8: Type "%ProgramData%" into the address bar. Windows XP: Type "%ALLUSERSPROFILE%\Application Data" into the address bar. 3. Hit Enter and open the [Malvern Instruments] folder from the folder list. 4. Right click the [Zetasizer] folder and select [Properties] from the menu. 5. Click on the [Security] tab. 6. Windows 7/8 only: Click on the [Edit] button beneath the "Group or user names" list. The "Permissions for Zetasizer" window should be displayed. 7. Under the "Group or user names" list, click on the [Add] button. The "Select Users or Groups" dialog should open. 8. In the "Enter the object names to select" box, type in "Everyone" and click on the [Check Names] button. The word "Everyone" should become underlined. 9. Click [OK] to accept and close the "Select Users or Groups" dialog. The group "Everyone" should be added to the "Group or user names" list. 10. Select the [Everyone] item in the list and tick the [Allow] box for the "Full control" option in the "Permissions for Everyone" list below. 11. Click [OK] to accept and close all properties windows. 12. The audit trail should now work correctly for all user accounts on this computer.	
Saving data to non-local fixed drives **It should be noted that the software does not support saving directly onto non-local drives unless the drive can be guaranteed to be 100% available. This is because the software is continually reading and writing to the active measurement file and if the connection to the drive is lost then the file can become corrupted and measurement data lost.**	It is suggested that users interact with a local file and then save this file to a network location once the session has been completed.	Hardware
It is possible to create a High Temperature dispersant (temperature above 92 degrees), for use on the High Temperature model of the Zetasizer Nano, which can	Ensure that any SOPs configured for a High Temperature Nano are not run on a standard Nano.	Software Bug

then be selected for use on the standard model. When the measurement is run, if the temperature is outside the range for the current model, a message will be printed in the log and the measurement will be performed at 25 degrees.		
When launching the Zetasizer software from a .dts file in Windows Explorer an error message will appear with the following txt: ***"There was a problem sending the command to the program"***	This error message does not stop the file from loading and can be safely ignored.	Software Bug

Other Issues of Note

Records and Analysis

The analysis algorithms for the calculation of size, zeta potential and molecular weight, including data filtering, are being continually improved. The effect of this is that if data taken from a previous version of software is edited, the result may change, even if only the sample name is edited. This is because the algorithms themselves are not stored with the record. This does not apply to parameters stored with the record such as the viscosity, and refractive index etc. as the same parameters are always used in the recalculation of the edited result.

This does not of course change the result of the stored record, as after editing a new record is created. To tell if a record is the original or has been edited, the parameter 'Is edited' can be added to a report or the record view. This can be found in the measurement audit information section of the parameters list. It will display 'False' if the record has not been edited.

Zetasizer APS and Zetasizer µV driver issues (Does not affect Zetasizer Nano series)

Version 6.30 to Version 6.34

The drivers included with the software for the 6.3x releases for the Zetasizer APS and Zetasizer µV are incompatible with some of the earliest instruments. This is expected to affect only Zetasizer µV. This issue manifests as an inability to connect to the instrument. These issues will be handled on a case by case basis and if identified, should be referred to Product Management via the Helpdesk.

Version 6.34 to Version 7.01 (Windows XP only)

Version 6.34 of the Zetasizer software updated the USB driver for the Zetasizer APS and Zetasizer µV instruments to version 20.2.0.5. However it has been noticed that this new driver is not fully compatible with Windows XP. Shutting down the computer with the instrument on and connected will result in it restarting instead. The solution to this problem is to turn off or disconnect the instrument before shutting down the computer.

Version 7.02 and beyond (Windows XP only)

Version 7.02 of the Zetasizer software updated the firmware for the latest Zetasizer APS and µV instruments. However, there is an issue reconnecting to these instruments after a disconnection with the Windows XP operating system. If the instrument is unplugged from the PC whilst the software is running then when the USB cable is plugged back into the same port, the software will fail to reconnect. The solution to this problem is to plug the USB cable into a different port, this should then allow the software to detect the instrument and connect successfully.

Creating and Editing Results in the Report Designer

Version 6.21 of the Zetasizer software updated the way in which reports were generated. The following procedure should now be followed whenever creating a new report:

1) If creating a new report or editing an existing report, the report title must be changed and ideally should also be unique, as it is this title, not the filename, which is displayed inside the workspace editor. To change the report title, edit the field in the report designer as shown in the following figure.
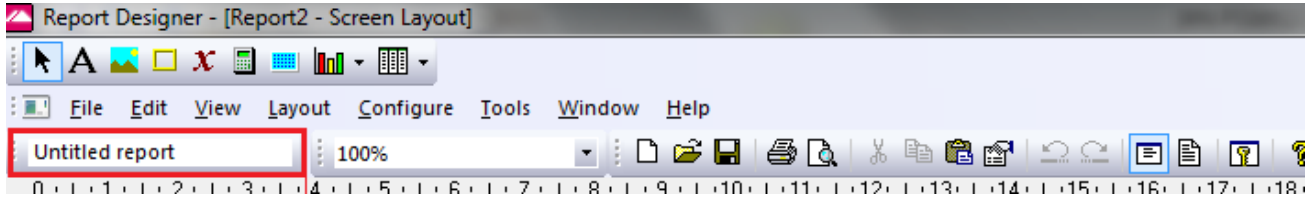

2) Once the report has been finished, in order for the software to load it, it needs to be saved into the Reports directory under the relevant language, i.e. it needs to be saved in the "Documents\Malvern Instruments\Zetasizer\Reports\en-US" or "Documents\Malvern Instruments\Zetasizer\Reports\ja-JP" directory depending on the language selected.

3) Once steps 1 and 2 are preformed then the new\updated report will be visible in the workspace editor inside the main Zetasizer software. Simply press the configure workspace button on the main toolbar and then go to the "Report Pages" tab.
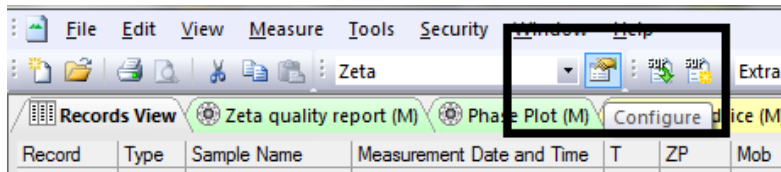
4) If there are any reports with duplicate titles visible to the software then they will be listed in the Report Pages tab with their file location.
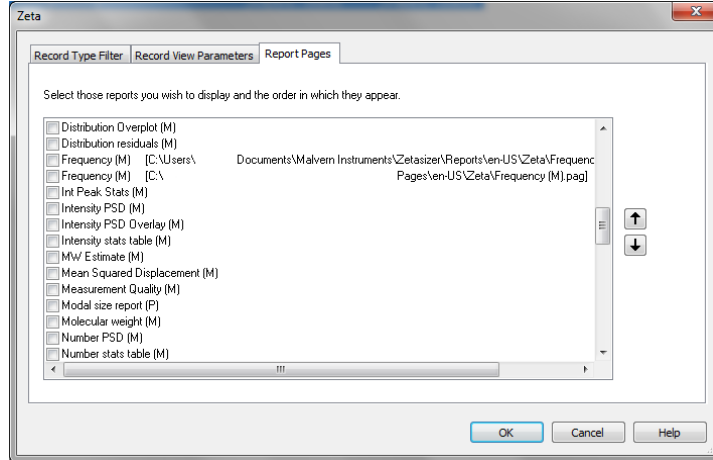

5) Only one duplicate report can be shown in the workspace at a time, if it is desirable to have both reports visible in the workspace then the title of one of the reports should be altered as outlined in step 1. If the user tries to select more than one report with the same title then the following warning will be displayed:
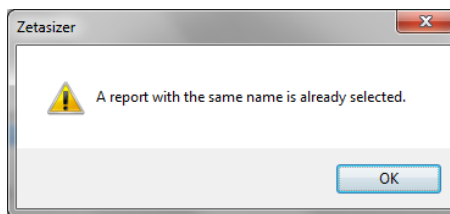
Viewing monomodal Zeta records in the Report view

When viewing zeta records created with the monomodal data processing analysis model, in a report, "No Data" will be displayed in any Zeta Potential specific charts. The charts should say "Monomodal Measurement" as there is data available. See example below.

Result quality : Good

Zeta Potential Distribution

No Data
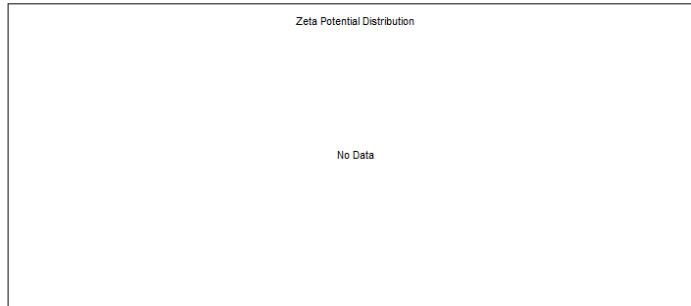
Customer deliverables

Application software suite

The software is contained on one CD-ROM. The disk is labeled PSS0012/36

- Operating software

- Zetasizer User manual

- MPT-2 manual

- NanoSampler User manual

- USB drivers

- Software Update Notification (SUN) with changes from previous software version (this document)

- Adobe Acrobat Reader

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