

ZS XPLORER SOFTWARE: v3.3 (PSS0048-20) SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of **ZS XPLORER software version 3.3** (**PSS0048-20**) for the Zetasizer Advance range of instruments. Here forward referred to as ZS XPLORER.

This release supports the Zetasizer Advance range of instruments only (including Pro (ZSU5800) and Ultra (ZSU5700) models).

ZS XPLORER is not compatible with the Zetasizer Nano series of instruments (Nano S90, Nano ZS90, Nano S, Nano ZS, Nano ZSE, Nano ZSP, Zetasizer μ V and Zetasizer APS) nor can it read the *.dts file format from the Classic Zetasizer series software 8.02 or earlier.

For the latest version of this document please check our website at - <u>https://www.malvernpanalytical.com/en/support/product-support/zetasizer-range/zetasizer-advance-range</u>

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 ZS XPLORER software, Windows 10 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.



IMPORTANT:

Only Windows 10 64-bit Operating System is supported

Microsoft user accounts are not supported

Before installation of the software, the instrument should be switched off and disconnected.

Regulated Environment customers upgrading to ZS Xplorer V2.3.1 or later, will need to also upgrade to OmniTrail and OmniAccess V1.4.

In some cases, the installer will require the user to restart the PC, in this case it is required that the Administrator logs in to the PC for the first time, following the restart. Failure to do so may cause the software to crash. In this case reinstalling the software on the Administrator account will fix the issue.





Recommended System Requirements

The recommended computer system requirements for running this software are highlighted in table 1 below.

Feature	Specification
Processor Type	8th Gen+ Intel Core i7 Processor (or better)
Memory	16 GB RAM
Solid State Drive	512GB or greater
Display Resolution	1920 x 1080 full HD screen resolution minimum
Connectivity	2 free USB2.0 or higher ports
Operating System *	Windows 10 64 bit. * The ZS XPLORER software is not compatible with 32-bit Operating Systems

Table 1 Recommended system requirements for ZS Xplorer software.

Supported operating systems

ZS XPLORER is compatible with Windows 10 (tested on Windows 10 1909 version or later). Only 64-bit Professional versions are supported.

ZS Xplorer has also been tested on Windows 11 Pro (22H2) with both core isolation mode enabled and disabled.

Supported Languages

- English (US)
- Chinese (simplified)
- Japanese

Installation Instructions

Installation process

The software suite is available as a web download. The downloaded extractor contains the ZS XPLORER Setup, License Manager Setup and .NET Framework 4.8 Setup files. License Manager and .NET Framework 4.8 are prerequisites of ZS XPLORER. even if you are not using OMNITRUST regulated environment software suite.

When the extractor is run (see figure 1) it will extract the required installers to a folder named 'MPInstallers' in the location the extractor is run. The folder and a readme, with important information, will be opened (see figure 2).



ZS Xplorer File Extractor			_		×
Maivern Panalytical	\Users\User B PLORER_2.0.0	Desktop" folder .277_EXTRACTOR.exe	2		
Extracting MPInstallers	s\ZSXPLORER	Setup_2_0_0_277 ALP	HA.exe		
		Pause		Cancel	

figure 1 ZS Xplorer Self-Extracting Installation files

Downloads → MPInstallers	
Name	III ReadMe.txt - Notepad
📙 Utilities	File Edit Format View Help
🧰 LicenseManagerReleaseNotes.pdf	IMPORTANT INFORMATION
🖏 LicenseManagerSetup_v1.3.1.exe	
🛱 ndp48-x86-x64-allos-enu.exe	- You must have administrator rights to install the software packages included
ReadMe.txt	- You must have Windows 10, 64-bit operating system - Microsoft user accounts are not currently supported
ZSXPLORERSetup_3_1_0_52.exe	 If using Windows domain user accounts, the user domain must match that of the PC License Manager is required to be installed and running for ZS Xplorer to install correctly. License Manager is a stand-alone installer and included in this self-extracting .zip file
	INSTALLATION INSTRUCTIONS
	 A folder containing the following files should have automatically opened LicenseManagerSetup LicenseManagerReleaseNotes ndp48-x86-x64-allos-enu ReadMe ZSXPLORERSetup
	If not, find the folder containing the 'ZS-XPLORER EXTRACTOR' - and look for a folder called MPInstallers.
	 Check whether or not License Manager is already installed on your computer. If this is the first time you are installing ZS Xplorer then License Manager is unlikely to be installed and must be installed first. To check - Click Start->Settings->Apps - In the section Apps & features type 'License Manager' in the search box
	If License Manager is found then select it to show the version number. Otherwise License Manager is not installed.
	You need to install License Manager first before you move to the next step if - License Manager is not installed - License Manager is installed and the version number is less than 1.3.1
	To install License Manager double click on the LicenseManagerSetup file to run installer.
	3. Once License Manager is installed please install ZS Xplorer by running the ZSXplorerSetup.
	4. If the installer displays a dialogue 'Microsoft .NET Framework is required to install ZS Xplorer - Double click on the 'ndp48-x86-64-allos-enu' file to run the Microsoft .NET 4.8 installer. - Follow the instructions and restart the computer - After restarting the computer run the ZSXplorerSetup again

figure 2 Extracted installation files and ReadMe file.



.NET Framework 4.8 Installation

Microsoft .NET Framework 4.8 component is a requirement for ZS Xplorer software to run correctly and must be installed prior to the installation of ZS Xplorer. If you do not have the correct version installed the ZS Xplorer installer will warn you and won't proceed until the correct version of .NET Framework is installed. Windows 10 versions from 1903 include .NET 4.8 or higher and will not require updating.

License manager Installation

The Malvern Panalytical license manager component is a requirement for the ZS XPLORER software to run correctly and must be installed prior to the installation of ZS XPLORER. Please note that users upgrading from 2.00 or later are not required to re-install License Manager. Those upgrading from ZS Xplorer vers.1.50 or earlier must install License manager.

ZS Xplorer Installation

During the installation process, you will be prompted with the following message (see **Error! Reference source not found.**).



figure 3 "Disconnect Zetasizer Unit" message

Note:

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

Microsoft C++ Redistributable

The Microsoft Visual C++ Redistributable must be installed for the ZS XPLORER software to run. This is installed during the ZS XPLORER software installation progress and under certain circumstances can involve the computer needing to restart. Completion of this stage of the installation can take a few minutes and may take over 10 minutes. Whilst these components are being installed a window such as below will be displayed, figure 4.



🔩 Microsoft Visual C++ 2010 x86 Redistributable Setup	\times
Installation Progress Please, wait while the Microsoft Visual C++ 2010 x86 Redistributable is being installed.	8
File security verification:	
All files were verified successfully.	
Installation progress:	<u></u>
Installing Microsoft Visual C++ 2010 Redistributable	
	Cancel

figure 4 Microsoft Visual C++ Redistributable Installation Window

ZS Xplorer Services

As part of the ZSX installation there are several Windows services and components that are installed. These are listed below:

Services Installed:

Display Name	Version	Description
Trends Analysis Service	1.3.14.7	Interface and analysis for trends services
Instrument Service	1.1.54	Instrument control layer
License Manager	1.3.1	Manages licensing for extended features, such as OmniTrust
Malvern Panalytical Cloud Service	1.3.0	Service that allows access to MP Smart Manager services
Malvern Panalytical Regulated Environment Service	4.1.1875	Authentication service via Windows Account Services
Trend Analysis Repository	4.4.3.0	MongoDB interface



Components Installed:

Name	Version	Description
ZS Xplorer	3.3.0.42	Main Application
.NET & ASP.NET	6.0.5	Software components used by Zetasizer and installed to remove OS dependencies
MongoDB	4.4.3.0	Database component
SQLite	3.8.10.2	Database component

Smart Manager

During installation of version 3.3 of ZS Xplorer you will be asked if you wish to enable Smart Instrument. This is the first stage in bringing additional Smart Manager Services to your Zetasizer Advance system.

If you have an internet connection and have chosen to make your instrument a Smart Instrument during the ZS Xplorer software installation, your instrument will automatically start uploading key parameters to Malvern Panalytical Cloud Services. We only collect low-level telemetry data from your instrument. We don't collect any of your actual test data, and we can't control your instrument remotely. Our helpdesk uses the telemetry data to help you faster in case of issues.

The data that we do collect is safe with Smart Manager – it's stored and processed securely on the Microsoft cloud. With more certifications than any other cloud provider, Microsoft is committed to security, transparency, and regulatory compliance. And our own information security management system also complies with the strictest international security standards (ISO/IEC 27001:2013).

You can check the status of your connection by locating the Malvern Panalytical Cloud Service application on the Windows Task Bar Tray then right click and choose status.

If you did not allow the service to send data to Malvern Panalytical during the ZS Xplorer software installation, you can simply right click the same application, then click register to do so later.

To find out more about Smart Manager Services go to <u>https://www.malvernpanalytical.com/en/connected-world/smart-manager</u>



USB Driver Installation

During the installation of the USB drivers, you may be prompted several times with a message as shown in figure 5.

📰 Windows Security	\times
Would you like to install this device software?	
Name: Zetasizer Interface Publisher: Malvern Instruments Ltd	
Always trust software from "Malvern Instruments Install Don't Install Ltd".	
You should only install driver software from publishers you trust. <u>How can I decide which device software is safe to install?</u>	

figure 5 Install USB window

This warning can safely be ignored as the software installation has been fully tested on Windows 10. Press **Install** to continue installation of the USB drivers.

Connecting the Zetasizer to the computer

When the software has been installed and the instrument has been connected via the USB port, and switched on, the ZS XPLORER software may need to upgrade the firmware on the Zetasizer, in which case the status icon on the lower right of the software screen will indicate such (see *figure 6*).



figure 6 instrument firmware updating status icon

Users should not disconnect or power off their PC or instrument during normal firmware updating. In some rare occasions the firmware may fail to update correctly, in such circumstances a notification will be displayed indicating the issue – please restart the instrument and software to reset and repeat the firmware upgrade process.

With the correct firmware version installed the Zetasizer will connect to the instrument. A successful connection is indicated with an icon in the corner of the software (see figure 7) showing green and with a tick.



figure 7 Instrument connected icon



Uninstall Procedure

The software can be uninstalled using the standard Apps & Features panel in Windows Settings.

Running the installer with the ZS XPLORER software running

If the installer is run whilst the software is running, the window in figure 8 will display.



figure 8 Running installer with software open

Connecting the MPT-3 Titrator to the PC

Ensure the computer is turned on and connected to a Zetasizer Advance system.

Connect the MPT-3 Autotitrator to the computer using the USB cable provided, ensuring that it is turned on. Click on the settings button in the top left corner of the ZS XPLORER software (see figure 9).



figure 9 Software options



Click Options and navigate to the Titrator tab as seen in figure 10.

	Home	Measure	Analyze	Report Designer	Instrument
Opt	ions				
Folde	ers Titrator				
Con	nection settir	ngs			
The t	itrator connectio	n settinas allow confi	auration of how the	titrator connection is detected by the	software.

figure 10 Titrator options page

On the COM Port drop down menu, select USB Serial Port (COMXX), as shown in figure 11. (Note that the COM port number and description may vary). If the titrator has been detected on this port, then a green tick will be visible (see figure 11).

Foldors	Titrator*
roiders	nuator

Connection settings

The titrator connection settings allow configuration of how the titrator connection is detected by the software.

COM Port:	USB Serial Port (COM7)	~	Titrator detected.



If the titrator is not detected on the selected COM port, then a red exclamation icon will be displayed with a message (see figure 12).

Connection settings

The titrator connection settings allow configuration of how the titrator connection is detected by the software.

COM Port:	Communications Port (COM1)	0	Titrator not detected.

figure 12 Unable to detect titrator

Once the titrator has been detected, click to save the settings.

Once the settings are saved an icon and a saved message will appear next to the saved COM port as shown in figure 13.



Folders Titrator

Connection settings

The titrator connection settings allow configuration of how the titrator connection is detected by the software.

COM Port: USB Ser	ial Port (COM7)
-------------------	-----------------

figure 13 COM port saved

The titrator icon at the bottom right of the screen should turn green indicating that the titrator is successfully connected as shown in figure 14.



figure 14 Titrator successfully connected

ZS Xplorer – Backup & Restore

What to backup

By installation default, this version of ZS Xplorer application uses C:\ProgramData\Malvern Instruments\ZS XPLORER and its subfolders for configuration and user created output files. For ease, we would suggest this is the simplest folder to backup and restore.

To create a backup, we recommend that you consult your IT department to select the best method to achieve this. For pharmaceutical regulated environments, you should also consult your validation department - as they may have specific compliance requirements, and/or recommendations. Backup frequency and type e.g., full, incremental, or differential, along with consistency checking, should be considered when choosing the most appropriate backup methodology.

Table 2 provides information on the location and details of the important files and folders used by ZS Xplorer as well as our recommendations on backing up of data.

It is at the discretion of individual organization to define a backup process that is appropriate to their needs and the criticality of their data.

All file types used by ZS Xplorer can be copied to a secure location, we recommend that this be done at times when the system is not in use. Backups should be full backups (not differential) and a history of backups is retained to avoid overwriting a good backup with a corrupt version.

How to restore

In this section we cover the two most likely reasons why you want to restore backup files. The first being accidental deletion of files, or to replacing corrupted files for a working installation of the ZS Xplorer application. The second reason might be because the primary drive, on which the ZS Xplorer application was install upon, has been replaced or a fresh operating system has been installed, both of which requires the reinstallation of the ZS Xplorer application.

🔚 Saved.



It is important to note that when reinstalling the ZS Xplorer application, the version being installed must be same or later, as some files may not be backwards compatible with earlier versions of the application software.

Scenario 1 - restoring files to an existing installation:

- 1. Make sure the ZS Xplorer application is NOT running.
- 2. Restore/copy the required files from your backup to the destination folder, replacing the deleted or corrupted file/s.
- 3. Start ZS Xplorer and verify the recovered file/s are working as expected.

Scenario 2 – restoring files for a fresh reinstallation of ZS Xplorer.

- 1. If your backup contains the complete ZS Xplorer folder, subfolder, and files, simply restore/copy this folder to C:\ProgramData\Malvern Instruments\. This folder will need to be manually created.
- 2. Install your existing version of ZS Xplorer or later.
- 3. Start the application as normal and verify everything works as expected and that the software connects to the Zetasizer instrument.

Table 2 - ZS Xplorer file structure

File Name File Extension Location		Location	Backup?
Cells	.data	%ProgramData%\Malvern Instruments\ZS XPLORER\Cells	Not required – auto-regenerated if deleted
Materials & Dispersants .data		Shared: %ProgramData%\Malvern Instruments/ZS XPLORER\Materials Individual: %userprofile%Documents\Malvern	Defaults are auto-regenerated, however can be user configured – backup recommended
Measurement data (export location)	.zmes	Location set via option in ZS Xplorer	This is a temporary export location only – so user discretion on importance of any files here
Methods	.zskd	Shared: %ProgramData%\Malvern Instruments\ZS XPLORER\Methods Individual: %userprofile%\Malvern Instruments\ZS XPLORER\Methods	Recommended if custom methods used
Reports	.zrep	Shared: %ProgramData%\Malvern Instruments\ZSXPLORER\CustomReports Individual: %userprofile%\Malvern Instruments\ZS XPLORER\Reports For reports with custom headers or logos, there is an additional folder: %ProgramData%\Malvern	Default reports auto-regenerated on deletion – recommended if custom reports used



pH probe calibration	pH probe .cal %ProgramData%\Malvern calibration .cal Instruments\ZS XPLORER\Titrator		Not necessary as can be re-calibrated
Scattering standard	.data	%Program Data%\Malvern Instruments\ZS XPLORER\ScatteringStandards	Recommended
Working file	.db	Shared: %ProgramData%\Malvern Instruments\ZS XPLORER\Working File Individual: %userprofile%\Malvern Instruments\ZS XPLORER\Working File	This is the main working database file that holds measurement records – highly recommended
Program data folder	various	%ProgramData%\Malvern Instruments\ZS XPLORER	This is the main programme data and can be restored by re-installation of the software
Titrator configuration	.xml	%ProgramData%\Malvern Instruments\ZS XPLORER\Titrator	Not required as can be readily set-up in ZS Xplorer
Storage configuration	.xml	%ProgramData%\Malvern Instruments\ZS XPLORER\WorkingFileSettings	Not absolutely required as can be set-up in ZS Xplorer
Studies	n/a	C:\Program Files (x86)\Malvern Instruments\TrendAnalysisData\data	Backup if performing Studies type measurements – see <u>https://www.mongodb.com/docs/manual/core/backups</u> for advice on backing up and restoring Mongo DB data



New Features & Changes

OmniTrust support

The Studies page now integrates with OmniTrust through OmniAccess and OmniTrail. Previously the Studies page was hidden if the system was running in an OmniTrust environment.

With this release, the Studies page will now be visible on systems running in an OmniTrust environment.

Permissions

ZS Xplorer now supports using OmniAccess to control permissions of the Studies page. Various permissions have been added to allow customers to control which user roles are authorized to perform actions in Studies.

A new Studies section has been added to OmniAccess (see figure 15).





Since Studies integrates with existing ZS Xplorer workflows, many of the permissions will require access to underlying ZS Xplorer permissions. For a list of permissions and any permission dependencies can be found in the ZS Xplorer Manual (accessible from the "home" page of ZS Xplorer software).

Auditing

Auditable Records

Studies

A study record consists of a small amount of data about a study, such as its name and description.

Trends

A trend record consists of all the data for a trend inside of a study, such as the trend options and any measurement configuration.

Trend results

A trend result record consists of all data for a result of a trend.



Supported Event Types

Electronic record created:

- Study This event is raised when a new study has been created from the Study builder page.
- Trend -This event is raised when a new trend has been added to a study, both when creating new studies or when adding to an existing study.
- Trend result This event is raised when a trend measurement completes, and the result data is saved by the system.

Electronic record modified:

- Study This event is raised when the header data for a study have been modified, this includes the study name and description fields.
- Adding, modifying or deleting a trend does not raise an electronic record modified event for the study. Instead, a dedicated event is raised for the trend.
- Trend This event is raised when a trend is modified, trends can be modified from the study builder page or by editing concentration points on the study overview page.
- Trend result This event is raised when a trend result is modified, trend results can be modified from the study analysis page by editing the concentration or toggling the outlier state.

Note: Audit events are only created when the user clicks the 'Save Analysis State' button.

Electronic record deleted:

- Study This event is raised when deleting a study, this will subsequently delete all trends inside of that study and the appropriate trend events will be raised.
- Trend This event is raised when deleting a trend, this will subsequently delete all trend results that make up the trend and the appropriate trend result events will be raised.
- Trend result This event is raised when deleting a trend that contains results, trend results cannot be individually deleted.

Electronic record creation aborted:

• This event is raised when a Trend measurement is run and then stopped either manually or because an error has occurred.

Viewing Audit Trail Reports

There are three audit trail reports that can be viewed in Studies, the Study report trail, a Trend audit trail, and a Trend Result audit trail report.

Study Audit Trail Report

The Study audit trail report is accessed on the Study Measure page via the "footprint" icon next to the Study name, (see figure 16).



St	tudies	Analyze	Report De	signer l	nstrument
	80	Study Name Re Stud	ły		
	Trend	ew audit trail report	e latex in Wate	er Back scatte	er 25°C

figure 16: Study audit report button

Clicking the "footprint" button will open a pop-out window display the audit trail report of the Study record and the changelog of changes to that record (see figure 17).

Study Na Re St	^{ame} tudy			
Polyst	Audit trail report			×
	Audit Report Audit H	istory		
25 mL	Re Study			~
1	The selected aud	lit trail report		Min.un.
	Report controls			
Polys	Report format		Standard	~
25				
mL	Report headers			
	Header name	Header value		
. Delve	Concerns record	//desktop-jvf94gi/Studies/6cd9d0f4-cad0-4831-8262-eb682cfd	4015	
e: Polys	Record identifier	6cd9d0f4-cad0-4831-8262-eb682cfd4015		
	Record audit trail integrity	Valid		
5	Record creation	Complete		
	Record data integrity	Valid		
-	Report events			
	Event name	Event value		
	Created	13 June 2023 14:20:29.316 +01:00 - Greg McElroy (Administra	ator)	
	System	DESKTOP-JVF94GI - ZS XPLORER 3.3.0		
	Event name	Event value		
	Modified	30 June 2023 14:02:45.631 +01:00 - Greg McElroy (Administra	ator)	
	System	DESKTOP-JVF94GI - ZS XPLORER 3.3.0		

figure 17: Study audit report

Trend Audit Trail Report

The Trend audit trail report is accessed from the Study overview page. This page will display all the Trends of the loaded Study. Each Trend has an audit trail which can be viewed by clicking the "footprint" button (see figure 18).





figure 18: Trend audit report button

Clicking this button will open a pop-out window displaying the audit trail report of the Trend record and the changelog of changes to that record (see figure 19).

Audit trail report	_			×
▲ Trend 22	Audit Report Audit H	listory		
Solvent scatter	Trend 22			*//
▲ Concentration (1.00)	The selected aut	dit trail report		din tu
Result (1.50)	Report controls			
Result (1.50)	Report format		Standard	~
Result (1.50)			Candard	
Result (10.00)				U
Result (10.00)	Report headers			*
Result (10.00)	Header name	Header value		
 Concentration (3.25) 	Concerns record	//deskton-ivf94ni/Studies/6cd9d0f4-cad0-4831-8262-eb682cfd4	015/Trends/a3h204cf-cd0e-4c84-927h-7a6aa7ade0d6	
 Concentration (5.50) 	Record identifier	a3b204cf-cd0e-4c84-927b-7a6aa7ade0d6		
 Concentration (7.75) 	Record audit trail integrity	Valid		
Concentration (10.00)	Record creation	Complete		
()	Record data integrity	Valid		
	Report events			
	Event name	Event value		
	Created	15 June 2023 12:28:44.043 +01:00 - Greg McElroy (Administra	tor)	
	System	DESKTOP-JVF94GI - ZS XPLORER 3.3.0		
	Event name	Event value		
	Modified	28 June 2023 17:00:32.235 +01:00 - Greg McElroy (MP Analys	t)	
	System	DESKTOP-JVF94GI - ZS XPLORER 3.3.0		
				*

figure 19: Trend audit report

The user can view the history of the Trend by clicking on the Audit History tab. This page displays the name of the parameter that has changed, the old value and the current value (see figure 20).



Audit trail report					×
▲ Trend 22	Audit Report Audit History				
✓ Solvent Scatter	Trend 22				*//
 Concentration (1.00) 	The audit history for the selected record				Alli. III.
✓ Concentration (3.25)	Changelog Item				
✓ Concentration (5.50)	Timestamp	28 June 20	23 17:00:32.174 +01:00		
 Concentration (7.75) 	Author	WL:DESKT	OP-JVF94GI:Greg McElroy		
 Concentration (10.00) 	Modifications				
Result (10.00)	Property Name		Old Value	New Value	
Result (10.00)	Trend\Trend settings\Trend name		Trend 2	Trend 22	
Result (10.00)					

figure 20: Trend audit history

Result Audit Trail Report

The Trend Results audit trail reports are contained within the Trend audit trail report described above (see figure 21).

Au	dit trail report	
,	Trend 22	Audit Report Audit History
	✓ Solvent Scatter	Q0 Result (1.50)
	 Concentration (1.00) 	The selected audit trail repo
	Result (1.50)	Report controls
	Result (1.50)	Report format
	Result (1.50)	
	Result (10.00)	
	Result (10.00)	Report headers
	Result (10.00)	Header name Header '
	 Concentration (3.25) Concentration (5.50) 	Concerns record //desktoj a5de-ff8
	 Concentration (7.75) 	Record identifier d733962
	A Concentration (10.00)	Record audit trail integrity Valid
	Concentration (10.00)	Record creation Complet
		Record data integrity Valid
		Report events
		Event name Event va
		Created 28 June
		System DESKT(

figure 21: Result audit selector



The Trend Results audit trail and changelog behaves the same as for the Trends. The user can select the Result from the tree-view and the report or changelog is displayed on the right, depending on which tab is selected (see figure 22).

Audit trail report					×
▲ Trend 22	Audit Report Audit History				
✓ Solvent Scatter	Trend 22				×//
 Concentration (1.00) 	The audit history for the selected record				.III.III.
 Concentration (3.25) 	Changelog Item				
✓ Concentration (5.50)	Timestamp	28 June 20	023 17:00:32.174 +01:00		
✓ Concentration (7.75)	Author	WL:DESK	TOP-JVF94GI:Greg McEiroy		
 Concentration (10.00) 	Modifications				
Result (10.00)	Property Name		Old Value	New Value	
Result (10.00)	Trend\Trend settings\Trend name		Trend 2	Trend 22	
Result (10.00)					

figure 22: Result audit history

Approving & Rejecting Trends

Trends can be approved or rejected, once a Trend has been approved or rejected the Results of the Trend will have the same action applied. E.g. approving a Trend will approve all Trend Results. A Trend can be approved or rejected using the green thumbs up or red thumbs down buttons (see figure 23).



figure 23: Trend approve & reject buttons

Following the workflow of the existing ZS Xplorer implementation, there is no visual indicator of whether a Trend/Trend Result has been approved or rejected. The auditor must view the audit trail of the Trend or Result to view the status. A Trend can be approved or rejected multiple times in a row, each action will create a audit event in the report, again this is to mimic the behavior of the existing ZS Xplorer implementation.

Record Integrity

When loading a Study, the data integrity is checked for all records that make up that study to ensure the records have not been modified or tampered with outside of ZS Xplorer.

If any records have been tampered with, each Trend that has failed the integrity check will display a warning symbol and will not allow the user to interact with any Trend. The user will not be allowed to edit the Trend or view the results of the Trend, however they will be allowed to view the audit trails reports and changelogs. (see figure 24).





figure 24: Restricted Study

The user will be able to, given the appropriate permissions, delete the individual trend. If all of the invalid Trends/Results have been deleted, the Study will be unlocked and the user will be able to access the full Study capabilities again.

Opening Study Restrictions

Studies that have been created with OmniTrust disabled cannot be opened when OmniTrust is enabled.

Likewise, Studies that have been created with OmniTrust enabled cannot be opened when OmniTrust is disabled.

In both scenarios the Studies will still be visible in the Study selector, however, they will appear greyed out. A tooltip will appear on hover over explaining that it is not possible to load a non-audited Study when auditing is enabled or that it is not possible to load a audited Study when auditing is disabled (see figure 25).



figure 25: Unaudited study disabled with auditing enabled



Unsupported features

The following feature are not supported in the initial release of OmniTrust for Studies (v3.3). It is possible that these might be added in the future if required.

- Import/export of Studies.
- 'Locking' of a study, trend, or result.
- UI feedback when approving/rejecting Trends.

ZS Xplorer Not Starting Due to SQLite - Journal files.

A file with a suffix of '-journal' is created when a DB write action is performed, once the write is complete the -journal file is deleted or zeroed (emptied). Occasionally customers were noticing that these files were not being automatically deleted, this was preventing ZS Xplorer from opening.

The cause of these files not being automatically deleted is unknown, but it is assumed the anti-virus on a customer's computer was locking the file at the point of SQLite attempting to delete the file.

This was only affecting the custom dispersants and custom materials databases, these have now been swapped over to use in-memory journaling, this is a fix that has previously been applied to the other SQLite databases used by ZS Xplorer.

Smart Manager Reports ZS Xplorer Version 0.0.0.0

Customers on ZS Xplorer have reported that their Smart Manager portal is reporting a ZS Xplorer version number of '0.0.0.0'. This was being caused by the fact that the Instrument Service is a standalone software component and had no mechanism to retrieve the correct ZS Xplorer version. Once the user opened ZS Xplorer, the correct version would be sent to the Smart Manager portal.

This issue has been addressed by having the ZS Xplorer installer write versioning information to the Windows registry, the Instrument Service now reports that registry value as the ZS Xplorer software version.

GAMP 5 Software categorization

In its standard mode of operation, the Zetasizer Xplorer software provides users with a series of standard interfaces and functions that enable the software to be configured to meet specific user business requirements. These interfaces include the ability to define Standard Operating Procedures (SOPs) for sample measurement and create report definitions using pre-defined functions. If users apply these functions, then the software can be considered to be a Category 4 product.

Security Advisories

The following section and table 3 detail any security updates that have been addressed in this release, including fixes for identified vulnerabilities.

Note:

We always recommend updating to the latest software version which will provide you with new features, bugfixes and most importantly, security updates.

Note:

Other products may also be affected by any issue described here. We recommend you regularly check the Software Updates Notifications (SUNs) for all your Malvern Panalytical products, and register on our website to receive updates.



Table 3 Security updates

Reference	Description	Recommendation
HEN-1042	Version 2.00 and earlier of the ZS XPLORER software contains a vulnerability which could allow an attacker to craft malicious measurement (.zmes) and schedule (.zskd) files. Loading one of these malicious files could result in arbitrary code execution. Version 2.10 introduces a fix to completely mitigate this vulnerability.	Upgrade to version 2.10 or later of the software. Never open files from an untrusted source, even if they appear to be non-executable.
HEN-572	Version 1.50 and earlier of the ZS XPLORER software contains a vulnerability in the reports feature which could allow an attacker to craft a malicious report file. Loading a malicious report file could result in arbitrary code execution. Version 2.00 introduces a fix to completely mitigate this vulnerability.	Upgrade to version 2.00 or greater of the software. Never open files from an untrusted source, even if they appear to be non-executable.

Changes and fixed issues

The main changes and issues fixed in this release of the software are listed in table 4.

lssue key	Summary	lssue Type
174609	Restrict builder/edit pages based on View studies/Run studies permissions	User Story
177543	Event Viewer Event Raised When Successfully Authenticating Trends	Bug
177887	Trend audit trail - Getting audit trail information	User Story
177889	Trend audit trail - Design and implement UI for audit trail	User Story
177894	Study audit trail - storing audit trail in the db	User Story
177895	System Audit trail - Signing	User Story
177896	System audit trail - Audit study on creation	User Story
178723	Trend Audit Trail - Implement approval rejection buttons	User Story

Table 4 changes and fixed issues in version 3.3 ZS Xplorer software



178724	System Audit Trail - Implement Trend approval rejection zsx methods	User Story
179975	Trends database - Add database layer objects	User Story
182683	Implement Trends System Audit Events	User Story
182685	Read & Write whole Trend entities	User Story
182686	Implement Trend Validation Status	User Story
183928	Implement Trend Changelog UI	User Story
184036	Implement Results changelog service	User Story
184037	Result audit trail - Getting audit trail information	User Story
187409	Smart Manager - Zetasizer software version reporting 0.0.0.0	Bug
187738	Keep user on trend builder page when cancelling RE dialogs	User Story
187740	Handle signing cancellations gracefully	User Story
187787	Connect Trends Changelog UI to Changelog Collection	User Story
188433	Prevent the Import and Export of Studies in RE mode	User Story
188436	Trend audits sometimes incorrectly show as invalid	Bug
189307	Results Audit Trail - Validate Study Solvent Scatter Result	User Story
190561	Update default Authorisation file for Studies	User Story
190763	Deleting invalid trends	User Story
191849	Implement study changelog service	User Story
192868	Studies Fails to Load if SSO is Enabled in OmniAccess	Bug



193949	Studies: Invalid Trend icon shows black border when clicked	Bug
194098	Disable Private Studies in RE Mode	User Story
194436	Studies - Unable to export studies data	Bug
194797	ZS Xplorer not starting due to presence of file: customMaterial.data-journal	Bug
195013	Remove the Results Audit Trail Report Button from the Study Analysis Page	User Story

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 where they are provided.

Reference	Severity	lssue	Workaround	
NA	Normal	Regulated Environment customers upgrading to ZS Xplorer v3.3 may need to also upgrade to OmniTrail and OmniAccess V1.4 if previous ZS Xplorer version earlier than v2.3.0	Check or Install Omnitrail V1.4 and OmniAccess V1.4 when using ZS Xplorer v3.2.2 in a regulated environment if upgrading from ZS Xplorer versions 2.3.0 or earlier	
TFS-182966	Normal	Reports: Parameters path does not fit in list box boundary	Edit report template to allow more room for the parameter to display correctly, if possible	
HEN-1971 TFS-180690	Normal	Concentration Trends - After selecting multiple measurements, starting the measurement, accepting the solvent scatter dialog, and leaving the confirmation dialog alone while the scattering count measurement completes, the concentration dialog is modal and blocks the confirmation dialog but if you try to abort the concentration dialog, nothing happens.	Accepting the concentration point and then clicking the OK will abort the trend	
HEN-377	NormalSoftware locks-up if you cancel a measurement during the enable for size step		None- force close the application	
HEN-1894 TFS-180691	Normal	Edit study button may not reactivate at the end of a measurement	Navigate to an intermediate page to refresh the status	
HEN-1866 TFS-180699	N-1866 Normal Concentration trends - Can't see count rate trace during solvent scattering measurement		If you are in doubt about the cleanliness of solvent or buffer, then run the count rate tool and record the attenuation and count	

Table 5 Known issues in ZS Xplorer version 3.2.1



			rate and use these as manual inputs.	
HEN-1922	Normal	In some edge circumstances user can edit study whilst measurement in progress – this is a bug in an underlying component	Do not edit studies whilst measurements in progress	
HEN-1899 TFS-180693	Normal	Studies not in order	No workaround	
HEN-1615 TFS-159682	Normal	ZS Xplorer hamburger menu can become obscured when in trends tab – issue with underlying component	No workaround	
HEN-1866	Normal	Count rate live display is not showing during Concentration Trend measurements	No workaround	
HEN-2140 TFS-180695	Normal	Studies wont load – opening ZS Xplorer and going straight to Studies tab may prevent loading of any saved studies	Click retry and if this fails re-start ZS Xplorer	
HEN-2026 TFS-180692	Normal	Whilst a measurement is running UI can become slow if user navigates to study selector	Avoid using study selector whilst measurements are proceeding	
HEN-2093 TFS-172158	Normal	If a user includes a custom dispersant in a study and then updates the dispersant the change is not pulled into the open study until a new study is created or ZS Xplorer is restarted	Avoid editing custom dispersants during creation or measurement of a study without restarting software first	
HEN-2095 Normal Aborting a concentration and then selecting all re-running will cause to previously aborted methods the first		Aborting a concentration trend measurement and then selecting all measurement points and re-running will cause the trend to start at the previously aborted measurement point and not the first	All measurement points are measured but may be confusing to users so be aware of issue.	
HEN-2288NormalCrash after publishing stu after renaming a study if t changed between measure		Crash after publishing studies measurements after renaming a study if the study name is changed between measurements	Clearing the method list in Measure tab after renaming a Study will prevent the crash/do not rename incomplete Studies	
HEN-2297 TFS-180672	Normal	Printing a custom report from Report Designer will only show graphs with single color	Print reports from Analyze-Reports tab to ensure correct behavior	
TFS-180671	0671 Normal Trend Builder return to defaults button may not always reset to defaults		Click return to defaults a second time resets them to defaults	



Error Reporting

Should persistent problems occur contact the local Malvern Panalytical Helpdesk. To speed up response time include all the following.

A full-screen screen shot of any error message and everything behind it.

Full description of what was happening at time of issue and ideally leading up to it.

Instrument serial number (e.g. MAL1060289), instrument serial number can be found inside the sample cell basin and on the instrument back panel.

The software version, which can be found as described in a section below.

The log information described below.

And, if relevant and possible, export the relevant measurement data as described in the last section below.

Extracting log information

If an error occurs, further information about the error can be found from the Windows Event Viewer.

Click the Windows Start Button.

Type Event Viewer and press enter.

Navigate to Applications and Service Logs/Zetasizer All Events.

The window will display the most recent errors that have occurred with the ZS XPLORER software.

Error information can be selected and then exported with the Save selected Events button allowing this information to be passed to the Malvern Panalytical team for troubleshooting.

The contents of the measurement log window are logged to file at Documents\Malvern Instruments\ZS XPLORER\logs

Software version

The Software Version is vital to determining the cause of problems. To retrieve the version number:

Click on Application Menu button (figure 19)



figure 19 Application Menu button



Click on the **About** button.

Read version number (figure 20)



Figure 20 Software Version Number

Extracting measurement data to send

In situations where the errors appear to be related to a specific record or records, the affected records can be exported from the software by selecting them and pressing the export icon, see figure 21, and send the *.zmes file to the Malvern Panalytical team for investigation.

La	ate	60				
	Dra	*				
	i	Qua	Result Type	Sample Name	Date	
	70					
1			Size	60nm latex	11/06/2018 14:49:44	
2			Size	60nm latex	11/06/2018 14:51:27	
3			Size	60nm latex	11/06/2018 14:52:36	
4			Size	60nm latex	11/06/2018 14:53:46	
•			Size	60nm latex	11/06/2018 14:55:10	

figure 21 Exporting selected record



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Software Update Notification for ZS Xplorer software v3.3 (PSS0048-20)