

# Best Practices for Importing Data with Sievers\* DataShare Elite Software

This document is intended to provide best practice guidance on how to import data from various Sievers TOC analyzers into Sievers DataShare Elite Software, while maintaining data integrity during the transfer of information. The following scenarios will be discussed:

- Direct data transfer from Sievers M500 Online TOC Analyzers
- Importing data from standalone Sievers M9 TOC Analyzers
- Importing data with Sievers DataPro2 Software

## Sievers M500 Direct Data Transfer

The Sievers DataShare Elite software has the capability to directly connect to any Sievers M500 Online TOC Analyzer on the same network and import the data from the analyzer.

### **Prerequisites:**

An ethernet connection must be configured and established on the analyzer. This will require a direct ethernet connection to the analyzer and an IP address configured for the system. To learn more about configuring a network connection, refer to the M500 Operation and Maintenance Manual in the "Configuring the Network Connection" section.

#### How it works:

**Automatic Data Collection:** If applicable, DataShare Elite software can be set to automatically schedule the import of the M500 analyzer database. The intuitive software can automatically detect any new or appended data for routine review.

To configure automatic importing, log into DataShare Elite with a user that has the permissions to import data files. From the Management section, select Auto Imports **(Figure 1)**.

Select the checkbox to enable auto import and then select the following:

• Import Every (Days): This is the frequency the software will automatically import the current data from the Sievers M500 TOC Analyzer.

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- Start On (current PC location date): This field selects the date in which the auto import will begin.
- Run At (current PC location time): This is the time you want to perform the action of importing the new data from the M500 TOC Analyzer. It is recommended that this time be chosen during a period of high reliability for the network.

## Importing data

- 1. On the right side of the screen choose the applicable data type you wish to import into the software by selecting the appropriate check box **(See Figure 2).** By default, they will all be selected.
- 2. Press "Add" to begin the process of connecting the analyzer.
- 3. Enter the IP address of the Sievers M500 TOC Analyzer in the IP Address section then press enter. The software will interrogate the TOC analyzer and retrieve the Analyzer Name, Type, and Serial Number.
- 4. Verify the information is correct and press "Save".

Management Auto Imports				⊜ 🛛 🛇
Import Scheduling         Last Auto Import S         Import Scheduling         Last Auto Import Enabled         Import Every (Days)         Import Start On (current PC locat)         Import Conduct         0:00		emove Test Connection	Import Data Types  All  Results  Verifications  Validations  Frors Audit Trail	
			Save	Revert

Figure 2: Auto Imports Options

**Manual Data Collection:** Log into DataShare Elite with a user that has the permissions to import data files. From the Data History tab, select Import **(Figure 3)**.

- 1. In the top right, select the Analyzers radio button for the correct source.
- 2. On the right side of the screen choose the applicable data type you wish to import into the software by selecting the appropriate check box. By default, they will all be selected.
- Press "Add" to begin the process of connecting the analyzer.
   Enter the IP address of the Sievers M500 TOC Analyzer in the IP Address section then press enter (Figure 4). The software will interrogate the TOC analyzer and retrieve the Analyzer Name, Type, and Serial Number. the Analyzer Name, Type, and Serial Number.

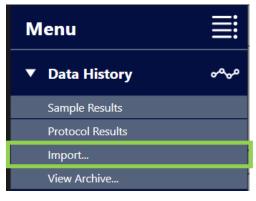


Figure 3: Data History Tab

4. Verify the information is correct and press "Import". The data import will begin.

🔳 Data Import					×
Source: 🔿 Files	Analyzers				Import Data Types
Analyzer Name	Analyzer Type	Analyzer S/N	IP Address		✓ All
			9		✓ Results
					✓ Calibrations
					✓ Verifications
					✓ Validations
					Errors
					🖌 Audit Trail
	_				
Add		Remove			
				Import	Cancel

Figure 4: Data Import

**Note:** The initial import process may take several minutes to complete depending on the amount of data in the M500 database.

The DataShare Elite software checks the current database for any duplicates or updates to existing data such as signatures to results. It will display if results were added or not imported and provide a description for files not added (**Figure 5**).

Import Results							>
Import Results							
Source	Added	Updated	Duplicates	Not Imported	Details		
M500 [0000]	$\checkmark$		$\checkmark$				
						c	ОК

#### Figure 5: Import Results

## Importing Data from standalone Sievers M9 TOC Analyzers.

The Sievers M9 TOC Analyzer with DataGuard allows remote data management of that analyzer if the analyzer is networked via an Ethernet cable. This function gives users the ability to remotely log into the system with their DataGuard credentials and back up, archive, or restore the database through a web portal over Ethernet connection.

#### **Prerequisites:**

DataGuard must be active on the analyzer and the User must be assigned the "Maintain System" user role, as well as, the applicable user role for the specific operation. For example, to restore the database, the DataGuard account includes "Maintain System" and "Backup Database." To learn more about DataGuard user roles, refer to the Sievers M9 Operation and Maintenance Manual in the "Using DataGuard" section.

An Ethernet connection must also be configured and established on the analyzer. This will require a direct Ethernet connection to the analyzer and an IP address configured for the system. To learn more about configuring a network connection, refer to the Sievers M9 Operation and Maintenance manual in the "Configuring the Network Connection" section.

A configured secure network folder that prevents deleting capability is required. The files that are generated are encrypted and can only be read by DataShare Elite software or the Sievers M9 TOC Analyzer. Restricting modification is not necessary. Users importing the software will need to be able to read the file to import its contents. Refer to your IT department to properly configure your network folder.

How it works:

- 1. Log into the Sievers M9 TOC Analyzer with DataGuard by opening an internet browser screen (such as Chrome or Internet Explorer).
- 2. Type the IP address followed by :1123. For example, type 3.112.203.80:1123. An M9 Web Portal screen will appear.

M9 Laboratory Web Port	
← → C O Not secure   3.112.203.80:1123/index	x 🖬 🖂 1
🔢 Apps 💿 Printer Install Files 🔯 Open 🛛 😨 JIRA 🗋 MyTime	39
M9 Laboratory Web Portal SERIAL NUMBER :0057 User Name	
Password	
Sign In	

Use a configured user, log into the analyzer with DataGuard credentials. This will give you access to perform the necessary backup or archive of the system. DataShare Elite can import both the database backup and archive files.

M9 Laboratory Web Port ×	
← → C ③ 3.112.203.80:1123/export?session=59920d8da6a371e5822639ac75b8603a	☆ 🖸 🖂 🗄
🔛 Apps 😨 Printer Install Files 🔯 Open 🏾 🙀 JIRA 🗋 MyTime	29
M9 Laboratory Web Portal SERIAL NUMBER :0057	sign out
BACKUP DATABASE: Backup ARCHIVE DATABASE: Archive	
RESTORE DATABASE Choose File No file chosen	

3. Perform the Backup or Archive by selecting the appropriate buttons. This will start a download onto the computer for the selected function.

You can view the encrypted file in a download found in the download folder. It should be identified by one of the following file types.

- BackupDB\_XXXX\_DDMMMYYYY\_SN.bak
- ArchDB\_XXXX\_DDMMMYYYY.enc

**Note**: XXXX is the last four numerical numbers of the analyzer's serial number. It will be followed by the Date the function was performed and a sequential number for the number of downloads that were performed that day.

- 4. Transfer the encrypted data file to ensure you do not create a second set of data in the secure network folder that was previously established to prevent deletion of the files.
- 5. Proceed to the menu for importing files into the DataShare Elite software. When importing the .bak and .enc file types, the DataShare Elite software verifies the integrity of the data through a cyclic redundancy check to ensure the file was not manipulated.

**Note:** Additional software or capabilities such as an event logger may be required to trace the file through the various steps.

# Importing Data with Sievers DataPro2 software

The Sievers DataPro2 Software allows users with the proper permissions the ability to backup and archive the database as encrypted files that allow the encrypted data to be automatically sent to a configured network folder. Backup files created are an exact copy of the database of the DataPro2 software. These are generally intended to protect TOC data from various risks and allow the data to be restored in the event of a catastrophic failure. The archive file transfers the data from the Sievers DataPro2 database to a long-term data retention platform, such as the Sievers DataShare Elite software.

## **Prerequisites:**

DataGuard must be active on the software and the User must be assigned the applicable user role for the specific operation. For example, to restore the database, the DataGuard account must have the "Backup Database" role assigned to the permission level of the user. To learn more about DataGuard user roles, refer to the Creating and Revising Access Levels section in the DataPro2 User Guide.

The computer that the Sievers DataPro2 software resides with should have a network connection and mapped network drive that is also accessible by the Sievers DataShare Elite software.

A configured secure network folder that prevents deleting capability is required. The files that are generated are encrypted and can only be read by the Sievers DataShare Elite software or the Sievers DataPro2 software. Restricting modification is not necessary. Users importing the software will need to be able to read the file to import its contents. Reach out to your IT department to properly configure your network folder.

## How it works:

The Sievers DataPro2 software allows users to automatically backup and archive data through the software.

- 1. In the configuration section, select the "Data Storage" tab and configure the appropriate backup and archive frequency.
- 2. Select the appropriate box to enable the automatic process.
- 3. Then select the browse button and navigate to the secured network folder.
- 4. Press accept to confirm the action.

**Note:** This process will need windows permissions to create and modify a windows task within the task scheduler.

ij DataPro2	- 0	×
•	Configuration	
	Configuration	

5. Navigate to the Secured network folder and confirm the creation of the appropriate backup or archive file.

## **Glossary**:

**Backup:** Copy of the entire System database as .bak file to allow restoring after a critical failure to prevent loss of data. Backup files will restore all data and settings from date of last backup. Backups can be restored on the deriving system, (overwriting data since last backup) or "read only" in DataShare Elite.

**Archive:** Process of storing historical data that is not actively used on a separate storage archive .enc file. Archive files can only be viewed by archive viewer in original system or DataShare Elite for long-term record keeping purposes and for maintaining compliance with regulations.

DataGuard: Sievers specific User and Audit management add on for 21 CFR Part 11 compliance.

#### References

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