


A stylized globe composed of a grid of small blue dots, centered in the background.

DataShare Elite Software

A centralized software program to support
data integrity compliance and efficiency



**Review & manage your Sievers
TOC and conductivity data in one
location from anywhere in the world**



DataShare Elite: The Sievers software program you've been waiting for.

Software to centralize data and provide compliance and efficiency while aligning with data and integrity requirements.

Data integrity is a key requirement for pharmaceutical manufacturing, and the desire to easily manage electronic data and metadata from a central location is often a specification for new software. Facilities must not only assure data integrity for compliance and its role in patient safety, but they must also strive to achieve the efficiency and productivity gains necessary to keep up with today's production demands. The ability to review and trend real-time data simplifies processes and allows release testing to happen much faster through secure, encrypted data transfer. Digitally signing records with accurate and customizable signatures means an even faster record review.

Simplified Data Storage

For life sciences customers, DataShare Elite software provides a single, central location to manage all of your Sievers total organic carbon (TOC) and conductivity data – pulling from multiple instruments, whether in the same location or across the globe. The intuitive software gives you the ability to make faster, more informed, and actionable decisions on your processes, all while meeting today's data integrity and data security requirements.

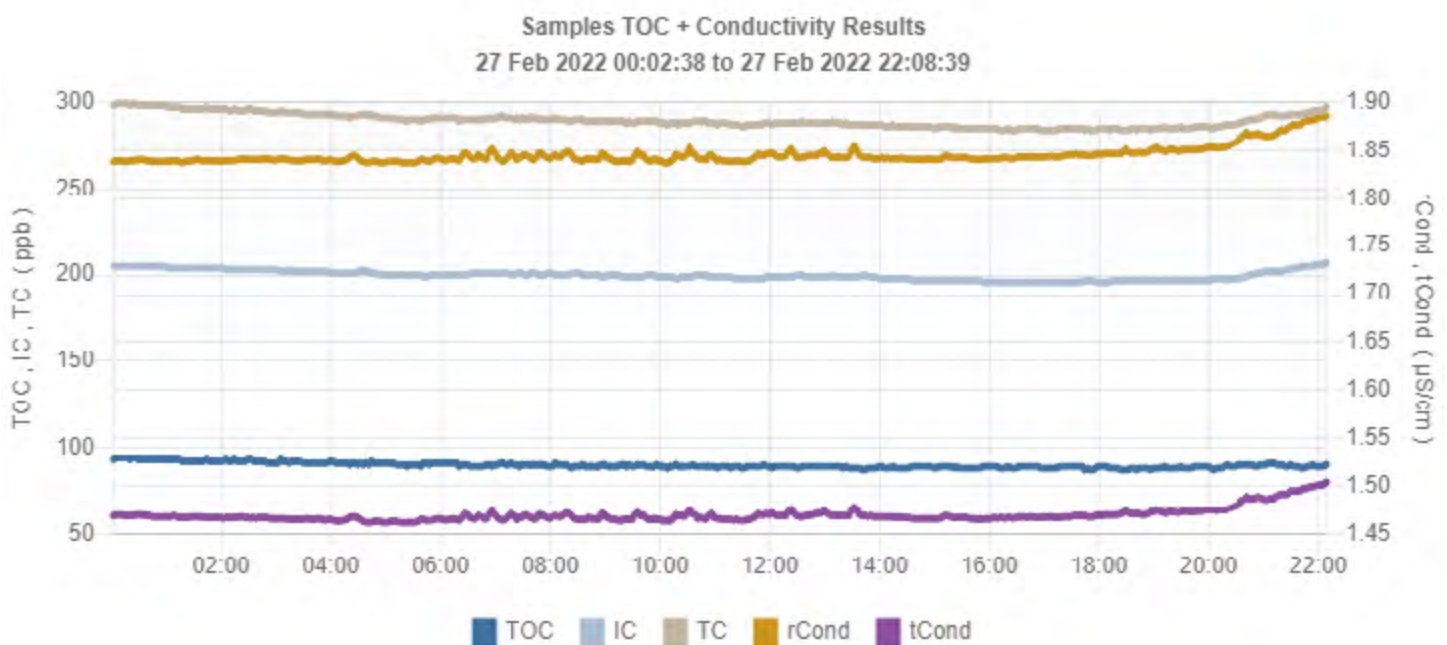
Sievers DataShare Elite software meets 21 CFR Part 11 compliance and follows ALCOA+ principles to ensure you are maintaining data integrity. Whether in the lab, or even remotely off-site, DataShare Elite gives you access to your data and the ability to view and electronically sign-off on reports.

- Store data in a secure location for easy audit access
- Track how each TOC analyzer is performing remotely
- Use Active Directory (AD) for login, review, and e-signing
- Achieve complete 21 CFR Part 11 and data integrity compliance

Applicable Sievers Instruments

DataShare Elite is compatible with all life science Sievers TOC instruments, even legacy devices, to alleviate the need to maintain multiple instances of software or legacy Windows installations.

- Sievers M9/M9e TOC Analyzers and associated DataPro2 Software
- Sievers M500 TOC Analyzers
- Sievers 900 TOC Analyzers and associated DataPro900 Software
- Sievers 500 RL TOC Analyzers
- Sievers CheckPoint (exported files can only be exported as .csv)



Graph 1: DataShare Elite can be used to remotely track process performance

Data Integrity

Sievers DataShare Elite software leverages comprehensive industry-leading data management tools to ensure data is secure. It supports full compliance to 21 CFR Part 11 and adherence to global regulations.

DataShare Elite provides a highly customizable enterprise solution with ALCOA+ data integrity compliance features and influence to cGMP guidelines using new data transfer, data security and data management features.

Data Transfer

- Remotely connect or import data over a secure network

Data Security

- Customizable Password protection
- Unique User ID requirements
- Data encryption
- Electronic signatures
- Easy import and review of audit trails
- Customizable access, roles, and permissions

Network-Based Data Management

- Closed system architecture
- Compatible with Active Directory (AD)
- Use with local server or an existing enterprise Microsoft SQL server
- Customizable data transfer and export

Enhanced Data Features

Remote Data Management

- Review instrument data remotely and electronically sign-off on:
 - Calibrations
 - Verifications & System Suitability Tests
 - Validations
 - Conductivity (if applicable)
 - TOC Sample Results
 - Audit Trail
- Easily search, filter, parse out data and save protocol results
- Manage and transfer data from the production environment and back for faster release of water systems
- Manage real-time data and audit trails as events happen

Data Visualization

- Qualitative and quantitative data
- Graphing and export capability

Secure Data Integration

- Easy to integrate into LIMS and MES systems



Available Configurations

- **Standalone:** Single computer being used to access instruments, includes up to 5 instruments. Uses Microsoft Express SQL Server. Users can purchase and add additional instruments up to 15 in total.
- **Enterprise:** Uses your existing SQL 2019 Enterprise, access to instruments remotely. Includes up to 10 instruments. Users can purchase and add additional instruments up to 50 in total.



System Requirements and Recommendations (based on Windows 10)

| | Minimum Requirement | Recommended |
|----------------------|--|--|
| RAM | 4 GB | Increase as database grows for optimal performance |
| CPU Speed | 1.4 GHz | 2.0 GHz |
| Available Disk Space | Standalone: 12 GB (2GB for DataShare Elite and SQL Server Express; 10 GB for SQL Server Express database) Client Only: 2 GB Enterprise Server: 8 GB for all features + room for data | |
| Screen Resolution | 1024 x 768 | 1920 x 1080 |
| Printer | Optional | |



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