

### Sievers\* M500

**Total Organic Carbon (TOC) Analyzer** 

accuracy. efficiency. integrity.



## The Sievers M500 Online Total Organic Carbon (TOC) Analyzer revolutionizes online detection of organics by bringing new performance, design, and data management features to the industry-leading Sievers TOC platform.

### **Advancing the Sievers Legacy**

The Sievers reagentless Membrane Conductometric TOC Detection Method delivers unmatched reliability, robustness, and accuracy for pharmaceutical Purified Water (PW) and Water for Injection (WFI) applications.

Sievers products have been leaders in TOC analytical instrumentation since the introduction of membrane conductometric technology to the market more than 25 years ago.

### **Superior Performance and Features**

The Sievers M500 is our third generation online TOC analyzer designed for **accuracy**, **efficiency**, **and integrity**.

Building upon the proven results of the 500 RL, the M500 improves our industry-leading performance and adds a suite of cutting-edge features:

- Super iOS 4-port sampler automates grab samples to increase efficiency.
- Reducing analysis time by 50% facilitates utilization of real-time data, early detection, and process control.
- 10-inch touchscreen enables faster and easier setup and operation.
- Standardized and customized protocols improve productivity.
- Enhanced data features improve data integrity.

# advancing the SIEVERS LEGACY

50% reduction in analysis time



### Sievers M500: Designed for Today's Data

The Sievers M500 leverages comprehensive industry-leading TOC data management tools to ensure data is secure.

The Sievers M500 supports compliance to 21 CFR Part 11 and adherence to US FDA and other Pharmacopoeia Data Integrity guidelines using new digital features:

### **DATA TRANSFER**

- Remote access
- Ethernet and WiFi
- Advanced communications using 4-20 mA, Modbus, Profinet, and binary

### **DATA SECURITY**

- Password protection
- Data encryption
- Customizable access, roles, and permissions

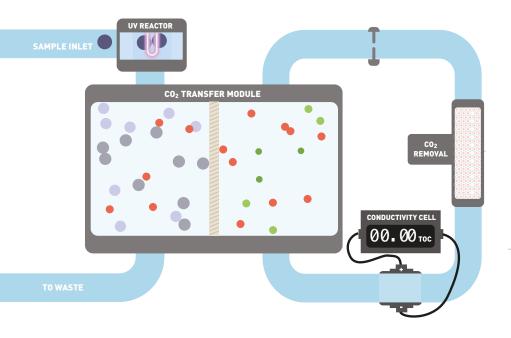
### **WEB-BASED DATA MANAGEMENT**

- Closed system architecture
- Customizable data transfer and export

## designed for DATA INTEGRITY

### Sievers Membrane Conductometric TOC Detection Technology

Proprietary gas-permeable membrane selectively passes only the CO<sub>2</sub> produced from oxidized organics



**Unmatched** reliability, robustness, and accuracy

**Higher** selectivity, sensitivity, stability, and precision

Discrimination between **organic and inorganic** carbon provides critical information for process control

### **LEGEND**

- Organic Carbon Molecule

### SIEVERS M500



### **Accuracy**

- Range: 0.03 ppb 2.5 ppm
- Limit of Detection: 0.03 ppb
- Limit of Quantification: 0.1 ppb
- Higher selectivity prevents interference from other compounds
- Measurements compliant to USP, EP, JP, IP, ChP, KP and all other harmonized compendia



### **Efficiency**

- 50% reduction in analysis time
- Simultaneous TOC & conductivity measurement
- Super iOS 4-port sampler
- Automated system suitability, calibration, & validation
- Adaptive auto-zero



### **Integrity**

- Designed for 21 CFR Part 11
- Remote access
- Advanced communications with Ethernet & WiFi
- Improved data transfer, data security, and data management

### **KEY FEATURES**

### COMPLIANT O

- US Pharmacopeia (USP)
- European Pharmacopoeia (EP)
- Japanese Pharmacopoeia (JP)
- Indian Pharmacopoeia (IP)
- Chinese Pharmacopoeia (ChP)
- Korean Pharmacopoeia (KP)
- All other harmonized compendia for TOC and conductivity analysis

### 10-INCH TOUCHSCREEN C

- Intuitive interface
- At-a-glance viewing
- Faster and easier setup & operation
- Chemical resistant

### SUPER IOS •

- 4-port sampler
- Automated calibration and protocols
- 2x faster results
- 50% faster validation protocols
- Reduced human error and labor costs



### DATA INTEGRITY •

- Supports 21 CFR Part 11 & Data Integrity regulations and guidance
- Lean compendia water analysis
- Simultaneous TOC & conductivity measurement

### ADVANCED COMMUNICATIONS O

 Ethernet, WiFi, 4-20 mA, Modbus, Profinet, Profibus, and Serial connectivity





### **Full Lifecycle Support and Services**

SUEZ provides a complete lifecycle solution for Sievers products. We offer a suite of tools and services to optimize your instrument from installation and validation, to operation and maintenance.

Trust Sievers validation services and Preventive Maintenance Agreements to provide peace of mind by ensuring optimal performance and providing the documentation required to support compliance, quality, and regulatory needs.

Our support team provides remote and onsite support for Sievers instruments. We are uniquely positioned to offer Failure Analysis Reports (FARs) to help close Out-of-Specification investigations faster and more efficiently.

INSTALLATION	VALIDATION	OPERATION	SUPPORT
<ul> <li>Field Service</li></ul>	<ul><li>Field Service Engineers (FSE)</li><li>Validation Packages</li><li>Onsite validation services</li></ul>	<ul> <li>Certified reference materials</li> <li>Vials and consumables</li> <li>Customized reference standards</li> <li>Preventive Maintenance Agreements (PMA)</li> </ul>	<ul> <li>Technical support</li> <li>Diagnostics</li> <li>Onsite repairs</li> <li>Failure Analysis Reports (FAR)</li> <li>Warranty</li> <li>Upgrades</li> </ul>



### Ask about Sievers Certified Plus full coverage service and repair

### **STANDARDS**

Accredited Certified Reference Materials

Standard Protocols

Low TOC Vials



Customized Reference Standards

**Customized Protocols** 

Dual Use Conductivity & TOC (DUCT) Vials

**CUSTOMIZED SOLUTIONS** 



### Certified Reference Materials and Customized Solutions

In addition to providing a wide range of accredited certified reference materials, SUEZ provides custom reference standards for your unique applications.

The Sievers M500 includes an expanded portfolio of instrument protocols as well as options to customize protocols for your application.



### **TOTAL ORGANIC CARBON**

TOTAL ORGANIC CARBON	
Linear Range	0.03 to 2,500 ppb as TOC
Accuracy	± 5% of measurement; ±0.1 ppb
Precision	± 1% of measurement; ± 0.03 ppb
Analysis Modes	Online, Online Averaged, Online Timed, Grab
Analysis Time <sup>1, 2</sup>	3 minutes for continuous online measurements
Ozone Compatibility	50 ppb O <sub>3</sub> continuous; 200 ppb O <sub>3</sub> for 2 hours daily
Sample Flow Rate (nominal)	0.25 mL/min
External Flow Rate	Minimum 50 mL/min
Sample Temperature	1-95°C (34-203°F) (withstands short-term steam exposure)
Sample Pressure	Up to 100 psig
Interferences	Insensitive to organic heteroatoms
Calibration Stability	Typically stable for 12 months
Display Readout	3 significant digits
CONDUCTIVITY	
Range	0.01 to 800 μS/cm
Accuracy	0.005 μS/cm or 1%, whichever is larger
Precision	≤ 1.0 % RSD
INSTRUMENT	
Power Requirements	100-240 VAC, 70 W, 50/60 Hz
Fuses	No user-replaceable fuses
Normal Operating Environment	Intended for indoor use only
Ambient Temperature	5-40°C (41-104°F)
Maximum Relative Humidity	Up to 95%, noncondensing
Maximum Altitude	3,000 m (9,843 ft)
Inputs	Two isolated binary inputs
Outputs	Serial (RS-232), one USB, three 4-20 mA, four alarms, one Ethernet
Installation/Overvoltage Category	II (protects against transients present in Category II power)
Safety Certifications	CE, ETL listed. Conforms to UL Std. 61010-1. Certified to CSA 22.2 No. 61010-1.
Pollution Degree	2 (normally only non-conductive pollution)
Display	Backlit 10.1 in, 1280 x 800, touchscreen display
Size	H: 43.4 cm (17.1 in) W: 55.9 cm (22.0 in) D: 28.7 cm (11.3 in)
Weight	16.3 kg (36 lb)
IP Rating	IP 55
Optional Wi-Fi	802.11ac/a/b/g/n Dual band 2.4/5 GHz
Industrial Communications Protocols	Modbus TCP/IP & Profinet (Included), Profibus (Optional)

<sup>&</sup>lt;sup>1</sup>Time to first measurement is 10 minutes.



 $<sup>^{\</sup>rm 2}$  Base model analysis time is six minutes for continuous online measurement.