laboratory, at-line, and online cleaning validation with Sievers M9 TOC Analyzers

Total Organic Carbon (TOC) and conductivity are two critical analytical methods that support Cleaning Validation, Verification, and Monitoring (CVVM). Testing for these analytical methods in support of CVVM can occur in the laboratory, on the manufacturing floor (at-line) or in a slip stream from the final rinse (online) of an automated cleaning cycle.

selecting the right Sievers* TOC Analyzer for your CVVM application

	M9 Laboratory TOC Analyzer	M9 On-Line TOC Analyzer	M9 Portable TOC Analyzer
Where is sample analysis completed?	QC lab	Attached to CIP skid	At-line, manufacturing area, or attached to CIP skid
Which sample types?	Rinse and swab	Rinse only	Rinse and swab
Who is taking samples?	Manufacturing, validation, or technical services	Sampling is automated	Manufacturing, validation, technical services, or sampling is automated
Who is performing analysis?	QC analyst	Analysis is automated	Manufacturing, validation, technical services, or analysis is automated

benefits of the Sievers M9 TOC analyzers

M9 Laboratory

- Fits into your current laboratory and data analysis testing scheme for efficient integration

Lean Analysis with TOC and Conductivity

- Combine two compendia assays into one
- Save hours of analyst time and increase productivity

Gain Productivity and Speed of Analysis

- Develop methods faster with Autoreagent mode
- Decrease Out-of-Specification (OOS) investigations due to environmental, sample handling, or transcription errors
- Optional Turbo mode decreases analysis time from two minutes to four seconds, saving hours on each Autosampler run

M9 On-Line

- No sample transport
- Enables process control (PAT)
- Continuously monitors the cleaning cycle
- Can be integrated with automation for immediate equipment release

Gain Productivity and Speed of Analysis

- Results in two minutes (standard mode)
- Optional Turbo mode updates TOC, IC, and TC measurements every four seconds, assuring that even short-lived excursions are captured
- Decrease Out-of-Specification (OOS) investigations due to environmental, sample handling, or transcription errors

M9 Portable

- Faster results and equipment release with a portable Analyzer
- Reduce sample transport
- Monitor multiple equipment cleaning cycles with a single instrument
- Enables process control (PAT)
- Quick troubleshooting of cleaning issues
- In-process testing
- Can be integrated with automation for immediate equipment release

Lean Analysis with TOC and Conductivity

- Combine two compendia assays into one
- Save hours of analyst time
- Increase productivity

Gain Productivity and Speed of Analysis

- Develop methods faster with Autoreagent mode
- Decrease Out-of-Specification (OOS) investigations due to environmental, sample handling, or transcription errors
- Optional Turbo mode updates TOC, IC, and TC measurements every four seconds, so you are never waiting for results

Also from Sievers – Validation Support Package

Simplify implementation with the **Validation Support Package for Cleaning Validation (CVD 50000-01)**. The package includes:

- Guidance
- Examples
- Worksheets
- Templates
- Sample Protocols

Contact your Sievers representative for more information.