your TOCnology
made for pharma

lab-loving people

multiWin pro for multi N/C x300 series

Data integrity based on ALCOA+ principles

analytikjena
An Endress+Hauser Company

1. Pure water. Precise data. Proven compliance.

Pharmaceutical production demands uncompromising control over cleaning validation processes and the reliable testing of purified water (PW) and water for injection (WFI). As expectations around digital data integrity and global regulatory compliance continue to rise, laboratories need technology that deliver accuracy, security, robustness, and complete traceability across the entire data lifecycle. This document provides a clear overview of how Analytik Jena's multi N/C x300 series, together with the multiWin pro software, support pharmaceutical laboratories in performing TOC (total organic carbon) and TN (total nitrogen) analyses. All workflows are designed to ensure full compliance, data security, and complete traceability.It also illustrates how hardware and software work hand in hand as a seamlessly integrated system. The result is reliable, audit-ready data across the entire measurement and documentation lifecycle — from sample introduction to final reporting.

“ I have been working with Analytik Jena TOC analyzers in pharma quality control for many years and very much appreciated the opportunity to participate in the beta test of the new multiWin pro TOC software. The compliance module meets the industry-specific requirements of FDA 21 CFR Part 11 and covers all data integrity requirements. I was particularly impressed by the user management and the easy-to-filter audit trail functions. ”

Thomas Beinicke, Head of Quality Control at EVER Pharma Jena GmbH

Make your TOC/TN applications easier with TOCnology made for pharma

- **More time for what matters**: Save time and minimize repetitive workload with minimum sample preparation, automatic acifidication, and long term stable calibration
- **As versatile as your challenges**: Adapt devices to your workflow with customized automation, high sensitivity, solid and TN options and FDA 21 CFR Part 11 compliance
- **A sustainable investment**: Optimize your costs with low reagent consumption, high uptime long-term warranties on core components, and minimal wear and tear.
- **Everything at a glance:** Analyze easily and compliant with multiWin pro enables supporting uninterrupted workflows, self-monitoring functions and detailed versioning and audit trailing.
- **A partnership that takes you further**: Analytik Jena provides robust, high-quality analyzers, a comprehensive service offering, and long-term availability of spare parts and support.

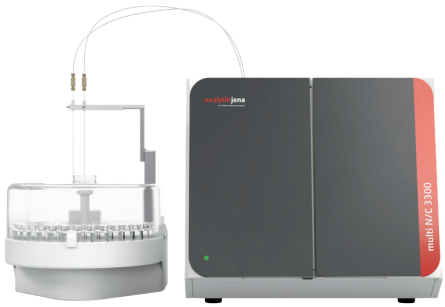
2. multi N/C x300 - your TOCnology for pharma

The multi N/C x300 devices are designed for TOC/TN analysis in the pharmaceutical industry. TThey are supporting TOC detection in ultra-pure water and extractables testing from packaging materials as well as TOC/TN analsis in cleaning validation and TN detection for total protein analysis, e.g. in vaccines The analyzers feature long term calibration stability and excellent reproducibility of data. Tailored automation options enable efficient high throughput workflows. All devices are easy to operate, robust and low maintenance. Integrated automatic blank subtraction enhances accuracy by eliminating background interference, while fully embedded System Suitability Test (SST) routines—compliant with USP <643>, Ph. Eur. 2.2.44, JP 2.59, and KP requirements—provide consistent, audit ready performance at every stage of TOC analysis.

multi N/C 4300 UV

Ideal for for water for injection (WFI), purified water (PW), ultrapure water (UPW) monitoring and TOC cleaning validation

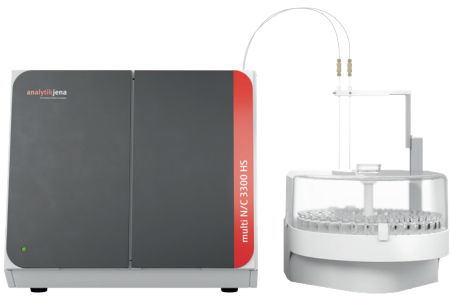
- UV oxidation-based TOC analyzer
- Persulfate-free in the trace range thanks to high oxidation power
- Automatic sample acidification and parallel purge in NPOC mode
- Low detection limits down to 1 ppb



multi N/C 3300

Ideal for TOC/TN cleaning validation, pure-water applications and extractables testing including swab combustion.

- High temperature TOC/TN combustion analyzer
- Automatic sample acidification and parallel purge in NPOC mode
- Detection limits down to 4 ppb
- Optional TN analysis by CLD detection



multi N/C 3300 HS

Perfect for WFI, PW, UPW monitoring and TOC/TN cleaning validation

- High temperature TOC/TN combustion analyzer
- Optional TN analysis by CLD detection
- Detection limits down to 4 ppb
- Optional swab test module for direct swab combustion

multi N/C 2300 N

Perfect for total protein determination via TN in vaccine quality control

- High temperature TN combustion analyzer
- Direct injection
- Smallest sample volumes down to 10 µL
- Equipped with chemiluminescence detector (CLD)

FDA 21 CFR Part 11 compliance module

With the FDA 21 CFR Part 11 compliance module, Analytik Jena's multiWin pro software enables TOC/TN analysis in compliance with international standards and pharmacopoeia methods. This software module is optionally available and is compatible with all multi N/C x300 analyzers operating under multiWin pro. For a demo or an offer, please contact

sales@analytik-jena.com

Controls of the multiWin pro compliance module for regulated environments

Feature	Description
Electronic Records	▪ Fully traceable, automatically generated electronic records ▪ Storage of complete raw data (integrated area units) and calculated concentrations ▪ Versioning of results, calibrations, and methods storing all values as well as date and time and originator of change. ▪ Meticulous, tamper proof, filterable audit trail ▪ Controlled database environment (CDM Service + PostgreSQL)
Electronic Signatures	▪ Three-step signature process: created, checked, released (and invalid). ▪ Enforced principle of dual control ▪ Applied to results, calibrations, SSTs, and methods. ▪ Dedicated user rights allowing use of methods and calibrations depending on status
System Controls	▪ Detailed user management with role based assignment of rights ▪ Configurable password rules & lockout policies ▪ Optional authentication against Active Directory/LDAP: user authentication only, no GPOs (group policy objects) ▪ Automated session logout ▪ Device, authority, and operational checks
Pharmacopoeia compliance	Dedicated and automated SST (System Suitability Tests) workflows and reports for: ▪ USP <643> Bulk Water and Sterile Water ▪ EP 2.2.44 ▪ JP 2.59 ▪ KP Annex 5

Free E-book "Compliant TOC/TN analysis in pharma".

Discover the most common pharmaceutical TOC and TN applications using our multi N/C x300 analyzers, and highlights how the FDA 21 CFR Part 11 Compliance module in multiWin pro, as well as the pharma-specific qualification, on-site software validation and other services.

Download here or scan the QR code.

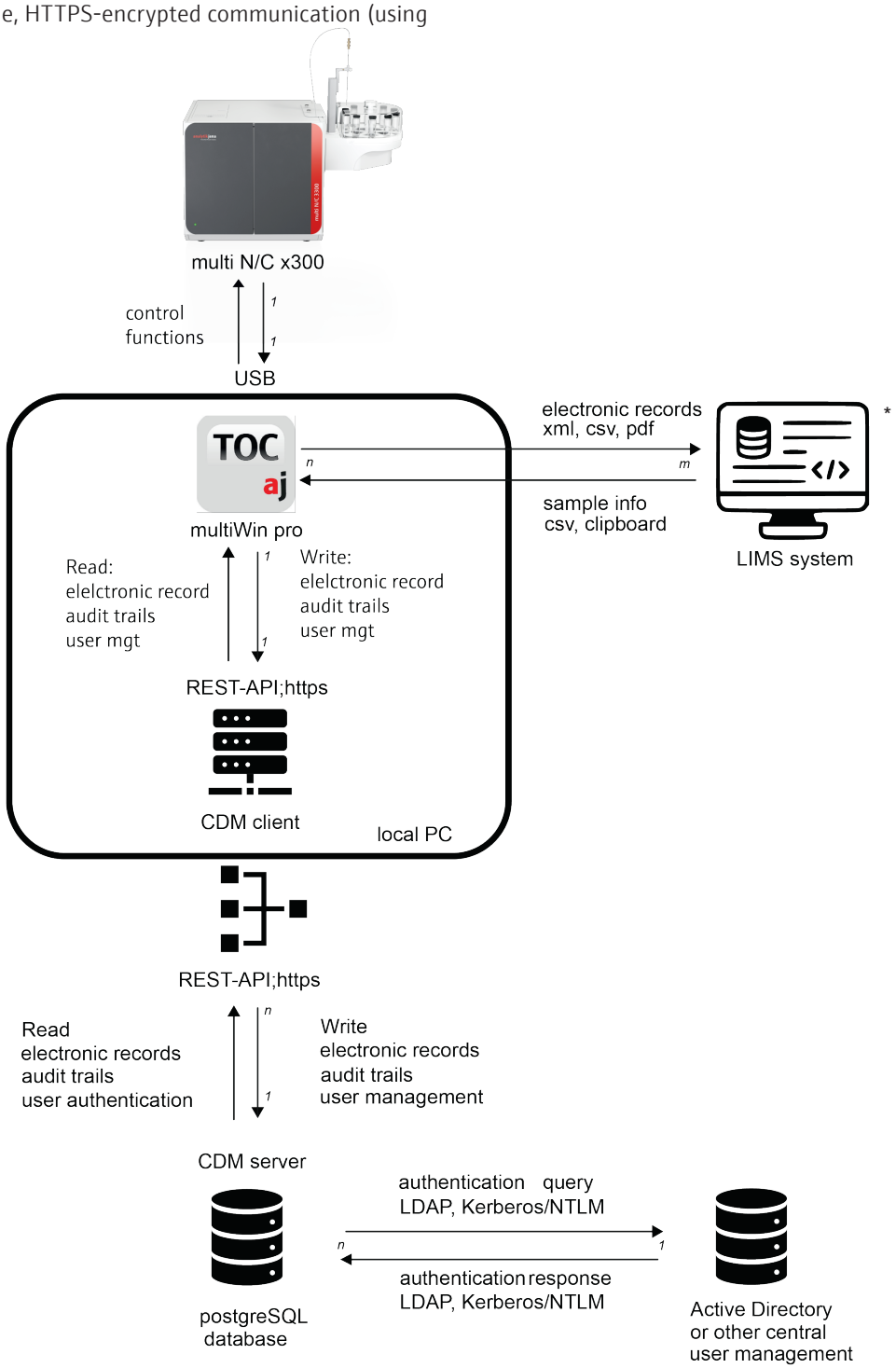
Data integrity according to ALCOA+ principles

Pharmaceutical production relies on the integrity of electronically recorded data. multiWin pro with the FDA 21 CFR Part 11 Compliance Module ensures that all data throughout the lifecycle is Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available: the global ALCOA+ standard for data integrity.

Feature	Description
Attributable	**Who did what and when?** ▪ Every Electronic Record is linked to the instrument serial number and logged in user ID. ▪ Changes are tracked in a new version with the changed values, date and time of change, and the changing user. ▪ User management with detailed, role-based rights assignment means only authorized users can act. ▪ All changes are documented in the audit trail.
Legible	**Readable and reproducible data over the whole product lifecycle** ▪ All data remains accessible over the whole product life. ▪ Clean, clear presentations of numeric, tabular, and graphical data. ▪ Reports available as PDF for audits and long term readability.
Contemporaneous	**Timely creation of records** ▪ Real time data capture & time stamped event logging. ▪ System clock synchronization ensures consistency.
Original	**Keeping raw data saved and available** ▪ Encrypted, tamper proof raw data storage in database. ▪ Raw measurement curves and integrals can be reviewed alongside calculated concentrations.
Accurate	**True, complete, valid, and reliable data storage with suitable process structures and control mechanisms** ▪ 64 bit floating point data handling for high resolution. ▪ Users can set number of decimal places to be shown (max. 16). ▪ Data input from instrument is verified. ▪ User actions are checked for validity. ▪ Changes of electronic records are tracked in a new version with the changed values, date and time of change, and the changing user. ▪ Data imports and exports are marked as such, and logged in the audit trail.
Complete	**Ensuring that all created electronic records are kept** ▪ All data (measurements, edits, events, comments) stored in one central database ▪ Electronic Records cannot be deleted, ensuring accessibility over the whole product life. ▪ Full chronological traceability.
Consistent	**All elements are time stamped and in chronological order** ▪ Automated, instantaneous record creation with time stamps ensures consistency in data. ▪ Electronic records can be sorted and filtered by date of first creation and date of last change. ▪ Audit trails can be sorted and filtered by date of creation. They cannot be paused or reset.
Enduring	**Availability of the data over the whole retention period** ▪ Secure storage in local or server databases (PostgreSQL). ▪ Permanent, tamper proof retention
Available	**Accessing data whenever needed** ▪ All data accessible for review, reporting, export (PDF/XML/CSV) at any time via authorized multiWin pro clients. ▪ Secure access for audits and inspections.

System architecture and data flow

In routine operation, data are generated on the **multi N/C x300** analyzer and acquired or processed in **multiWin pro**. When equipped with the **FDA 21 CFR Part 11 Compliance Module**, the system utilizes a **Central Data Management (CDM)** service and a **PostgreSQL** database within the customer's secure network to ensure tamper-resistant data storage, HTTPS-encrypted communication (using a customer-specific certificate), and centralized user management with optional **LDAP/Active Directory integration**. Data **exports** to **PDF, XML, and CSV** facilitate inspections, reviews, and system-to-system data exchange (e.g., LIMS/MES). Backup and restore operations are performed at the database level.



* icon by Wahyu A

Figure 1: Data flow diagram for the system of multi N/C x300 series analyzers with multiWin pro and central data management (CDM).

multi N/C x300 – your compliance master plan

Easy and compliant quality assurance (QA)
The system ensures complete traceability through standardized workflows, supports electronic signatures and review processes, and enables tamper-proof document generation.

IT-Security
Robust user management ensures that roles and access rights are clearly defined and securely administered. Communication is fully encrypted to protect data integrity during transfer, while database-level access control provides an additional layer of security directly at the source. Flexible options for setup, backup, and maintenance further support smooth deployment and reliable long-term operation.

Audit-ready
A transparent audit trail provides full visibility into all relevant actions, ensuring accountability and traceability throughout the workflow. Standardized PDF reporting supports consistent and review-ready documentation, while alignment with ALCOA+ principles strengthens the reliability and completeness of recorded data. Clear evidence of system validation and established data-integrity measures further reinforces compliance and builds confidence in the overall process quality.

Convenient operation in your lab
Save time and staff deployment through intuitive operation, supports automated workflows and sequences, and streamlines SST and calibration routines.

A partnership that takes you further: cooperating with Analytik Jena

With Analytik Jena, pharmaceutical manufacturers gain a reliable source for TOC/TN solutions in product quality control and process monitoring. Our quality philosophy and commitment to customer aims at a a common goal: to make your TOC/TN monitoring processes simpler, safer, and more efficient by providing excellent, long-living solutions and pharma-specific services that have your back.

Being part of the family-owned Endress + Hauser corporation, we focus on reliable long-term partnerships supporting future-ready pharmaceutical production.

Benefit from a trustful partnership:
- 30 + years experience in TOC/TN device manufacturing
- Long-term availability of products, spare parts and services
- A stable qualified supply chain with sustainable lifecycle concepts for future-proof investments
- Software developed under ISO 9001 with validation packages available
- High quality instruments designed for pharmaceutical water testing & cleaning validation
- Global service, validation support, and GMP compliant documentation

Services designed for you

Services
In pharmaceutical production, timelines are tight, and testing and monitoring systems must operate with consistently high reliability. Our service offering is designed to ensure full regulatory compliance, full traceability, and maximum instrument uptime.

Our service experts are trained and certified to deliver GMP-compliant services to make sure your processes and lab tests run safely and without interruption.

We provide a comprehensive service package including:
- Installation (IQ) and operational qualification (OQ)
- Software validation
- Audit trail with detailed service reports
- Short reaction times for troubleshooting
- Tailored service and maintenance packages

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