

TOCnology for Pharma

multi N/C x300 devices

Compliant
quality control
in pharma

analytikjena
An Endress+Hauser Company

TOCnology Made Compliant

Data integrity with multiWin pro

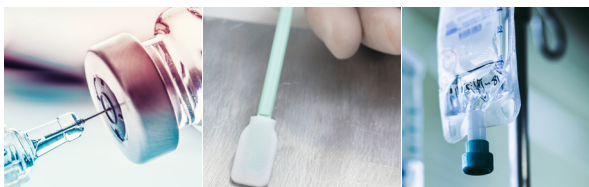
Achieve full data integrity and compliance with the new FDA 21 CFR Part 11 compliance module of the device software.



- ✓ **User management**
Tailor access and editing rights for your team members via user roles. Simply manage and monitor who does what and when.
- ✓ **Central data management**
Store the data from multiple instruments centrally and access them from any computer with multiWin pro installed.
- ✓ **Audit trail and versioning**
Track the time, author and details of each action (including changed values). Easily review changes on data and methods based on previous record versions.
- ✓ **Electronic signatures**
Formally document the three-step process „created - checked - released“ following the dual control principle. Ensure only released methods and calibrations are used.
- ✓ **System Suitability Test**
Carry out SST measurements with predefined sample sets and automatic result evaluation according to USP <643> bulk water and sterile water, EP 2.2.44, JP 2.59, and KP.
- ✓ **Qualification and validation services**
Get started sooner with equipment qualification (DQ, IQ, OQ, PQ) and on-site software validation.

multi N/C x300 Analyzers

Find the right device for your application



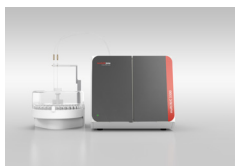
multi N/C 4300 UV

UV-based TOC trace detector for ultra-pure water and cleaning validation applications featuring persulfate-free sample digestion.



multi N/C 3300

High throughput TOC/TN analyzer featuring automatic sample acidification, suitable for pure-water and cleaning validation applications.



multi N/C 3300 HS

Ultra-sensitive TOC/TN analyzer for ultra-pure water and cleaning validation supporting direct swab combustion.



multi N/C 2300 N

Direct injection TN analyzer - best choice for small-volume samples in total protein determination. Equipped with CLD detector.



Compliance with standards and guidelines:

- GMP, ICH Q7
- FDA 21 CFR Part 11
- TOC: USP <643> bulk water and sterile water, USP <661>, EP 2.2.44, JP 2.59, KP
- TN: USP <1057>, EP 2.5.33, JP XVIII <G3-12-172>

All-round Carefree Package

Throughput, compliance, and service

Take the strain out of your TOC/TN analysis! Achieve data integrity, reproducible results, and worry-free operation with your analyzer, software, and comprehensive service package.



Our services for regulated environments

- Equipment qualification (DQ, IQ, OQ, PQ)
- Software validation
- Modular service contracts
- Personal hotline available 7 days a week
- Guaranteed reaction time as part of your contract

Discover more in our e-book!

Read our application notes on vaccine quality control, cleaning validation, and much more as well as information on our pharma-compliant software and services.



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