QbD1200+ Total Organic Carbon Analyzer

Reliable Measurement Made Simple

ACCELERATING *answers*

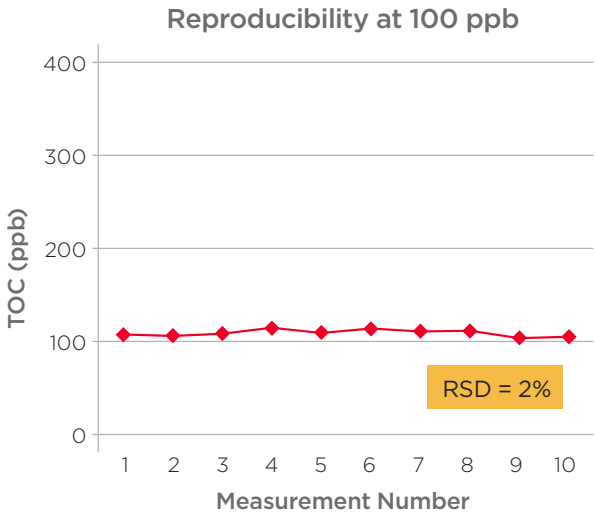
BECKMAN COULTER
Life Sciences

The QbD1200+ Analyzer

Delivers the highest performance with unparalleled ease of operation and maintenance

Reliable Data

- Stop throwing away your first sample - The QbD1200+ analyzer has virtually eliminated sample-to-sample carryover
- Outstanding reproducibility means more consistent data
- Dynamic Endpoint Detection ensures:
  – Complete removal of inorganic carbon
  – Complete oxidation of organics
- No additional inorganic carbon removal module required
- Digital Nondispersive Infrared (NDIR) detector automatically corrects background and drift for long term stability
- Optimized for pure water, water for injection and cleaning validation with a range up to 100 ppm

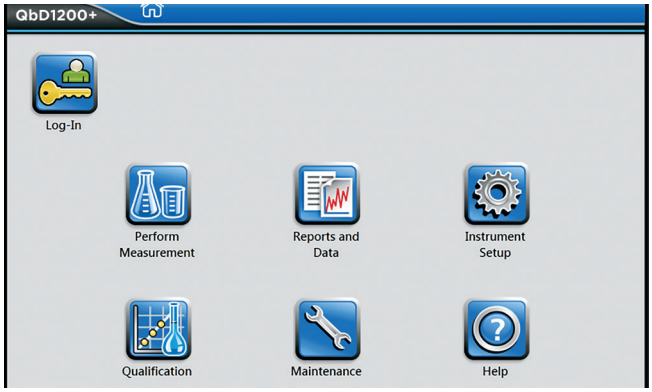


Total Organic Carbon

Total Organic Carbon (TOC) is an indirect measure of organic molecules present in pharmaceutical waters measured as carbon. A number of acceptable methods exist for analyzing TOC. The QbD1200+ analyzer uses a proprietary technology that oxidizes the organic carbon into carbon dioxide, which is measured to determine the organic carbon concentration. The QbD1200+ analyzer strictly adheres to the regulatory requirement of discriminating between inorganic and organic carbon.

Simplify Your Validation and Analysis

- Unbox your QbD1200+ analyzer and have it up and running in less than an hour
- No external PC required means no extra computer system validation for 21 CFR Part 11 compliance
- Large 10.4-inch color touchscreen display and intuitive user interface
- Automated calibrations, system suitability testing, and report generation
- User interface guides operator through steps; no need to refer to a complex manual
- Auto-ranging/auto-dilution means there is no need to know the sample concentration ahead of time
- Only one reagent is needed for ALL analysis



Low Cost of Ownership

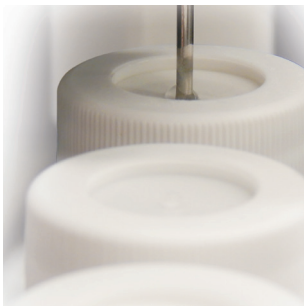
- Say goodbye to frequent maintenance
- Reduced service calls
- Buy your reagent from Beckman Coulter Life Sciences, or make your own (instructions provided)

Fast Calibration

- Automated calibration in approximately 90 minutes

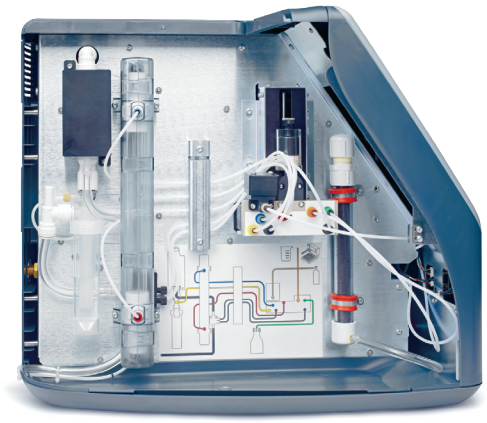
Unexpected, Over-ranging Samples are No Problem for the QbD1200+ Analyzer

- Glass reaction chamber is flushed out effectively after each measurement
- Recover from over-ranging sample (10x upper limit) on the very next measurement
- No special servicing or cleaning required after over-ranging sample



Quality By Design

- On-demand and automatic self-health check runs each time the instrument is powered on
- Automatic monitoring of pressure, liquid flow, gas flow, UV lamp intensity, temperature and NDIR detector via sensors at 10 points in the instrument
- Communicates proper functioning of all sub-systems ensuring reliable measurement and providing confidence in the test

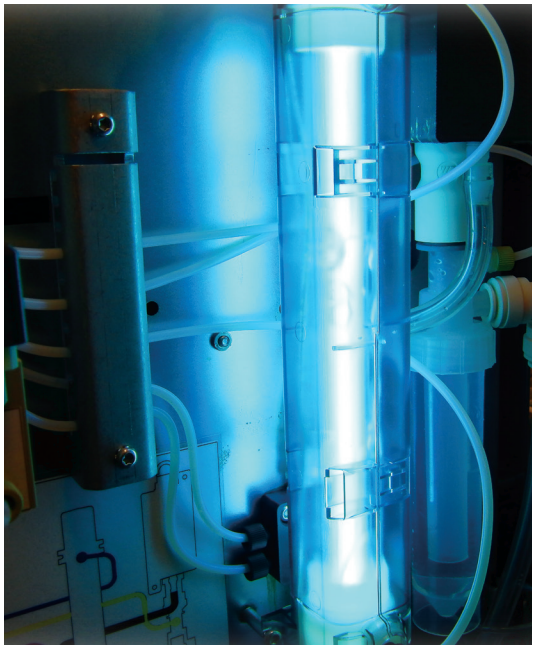


Ensure Regulatory Compliance with the QbD1200+ Analyzer

- Fully complies with all global pharmacopoeia regulations: USP, JP, EP, IP, KP, ICH
- Simple IQ/OQ/PQ qualification routine, compliant with ICH guidelines
- Convenient automated routines for:
  - USP SST Bulk Water
  - USP SST Sterile Water
  - JP SDBS Validation
  - Calibration with JP compliant KHP

Secure and Easy Data Management

- Designed to support 21 CFR Part 11 compliant workflows
- Export password-protected PDF electronic record directly from the instrument using Lightweight Directory Access Protocol (LDAP)
- Send data and reports to a single location for centralized record keeping
- Integrated hard drive encrypts all data with ample storage for a lifetime of measurements
- Create reports with the touch of a button



PERFORMANCE	
Range	0.4 ppb – 100,000 ppb
Detection Limit	0.4 ppb
Precision	< 2% or 3 ppb (whichever is greater)
Accuracy	± 2%
Calibration Time	120 minutes
Analysis Time	15 minutes; 4.5 minutes in Fast Mode
Sample-to-sample Carryover (from 500 ppb to blank)	0.1%
Overload Recovery (from 1,000 ppm to 1 ppm)	1 measurement

INORGANIC CARBON HANDLING	
Extra Inorganic Carbon Removal Module needed for samples with high levels of Inorganic Carbon	NO
Dynamic Endpoint Detection to ensure complete Inorganic Carbon removal	YES

INSTRUMENT SELF-DIAGNOSTICS TO ENSURE DATA INTEGRITY	
Instrument will report TOC value IF:	
Lamp intensity too low	NO
Carrier gas insufficient / tank runs out	NO
Reagent insufficient / bottle empty	NO
Sample volume insufficient / vial empty	NO

REAGENTS	
Reagent Supply	Purchase or make your own
Option to prepare own reagents	YES
Total number of reagents (acid, oxidizer, dilution water)	One (1)

MEASUREMENT METHOD AND ASSURANCE	
Oxidation	UV lamp + persulfate
UV Lamp Monitoring	Broadband silicon photodiode sensor
Detector	Digital NDIR
Detector Stability	Continuously verified against reference
Pre-Detector moisture removal	Peltier cooler with continuous current monitoring
Dispense Module	Syringe pump, accurate to +/- 1% volume
Flow Sensor	Dynamic fluid detector (ensures accurate sample and reagent volume)
Carrier Gas Options	CO_2-free air, O_2 or N_2
Carrier Gas Pressure Monitoring	Dual orifice pressure sensor
Carrier Gas Valve Shutoff	When measurement complete, valve closes to avoid wasting gas
Autorange Capability	Yes
Analysis Mode	NPOC (Non-Purgeable Organic Carbon)

DATA STORAGE AND RETRIEVAL	
Regulatory	21 CFR Part 11, all measurements recorded to encrypted database
Paperless Reporting	Password-protected PDF electronic record using Lightweight Directory Access Protocol (LDAP)
Input and Output	3x USB, 1x Ethernet
Data Export Formats	PDF, CSV

USER INTERFACE	
Display	10.4-inch high-resolution color touchscreen
External PC	No external hardware / PC required
External keyboard / mouse	Optional, not required
Ease of Operation	Intuitive user interface, step-by-step software guidance

QUALIFICATION ROUTINES	
Calibration	Automated routine: 18-point calibration using KHP (6 concentrations, 3 replicates each)
Calibration Standard	5ppm KHP (single 125mL bottle), diluted to achieve 1, 2, 3, 4, 5 ppm concentrations; reagent is used as blank
Verification Tests / System Suitability	Automated routines: • USP SST Bulk Water (blank, 500 ppb as C: sucrose, benzoquinone) • USP SST Sterile Water (blank, 8 ppm as C: sucrose, benzoquinone) • JP-16 <2.59> validation (blank, 500 ppb as Carbon SDBS)

REGULATORY COMPLIANCE SUPPORTED	
USP <643> (including Sterile Water SST), JP-16 <2.59>, EP <2.2.44>, IP, CP, KP, US EPA 5310c	YES
21 CFR, part 11	YES
ICH guidelines for instrument validation including: accuracy, precision, LOD, LOQ, linearity, range, specificity, robustness	YES, included in Performance Qualification

AUTOSAMPLER	
Capacity	64 sample vials (standard 40 mL glass TOC vials)
Style	XYZ, septum piercing
Sample tray material	Anodized Aluminum

GENERAL TECHNICAL DATA	
Instrument dimensions	W 320 x D 507 x H 410 mm
Instrument power requirements	12V D.C. from 100-240V A.C. adapter (included in ship-kit)
Instrument Weight	14 kg (31 lbs)
Autosampler dimensions	W 366 x D 537 x H 457 mm
Autosampler power requirements	100-240 VAC, 47-63 Hz
Autosampler Weight	21 kg (45 lbs)
Operating temperature & humidity	5-35°C; up to 90% relative humidity, non-condensing
Reporting units	µg/L (ppb)

In the interest of improving and updating its equipment, Beckman Coulter Life Sciences reserves the right to alter specifications to equipment at any time.

For Beckman Coulter's worldwide office locations and phone numbers, please visit Contact Us at beckman.com
2023-GBL-EN-100845-v2