

QbD1200

TOTAL ORGANIC CARBON ANALYZER

RELIABLE MEASUREMENT MADE SIMPLE.



Discovery
in motion.

 **BECKMAN
COULTER**
Life Sciences

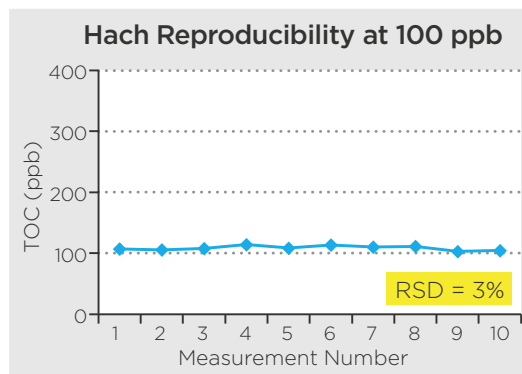


The **NEW** QbD1200

delivers the highest performance with unparalleled ease of operation and maintenance

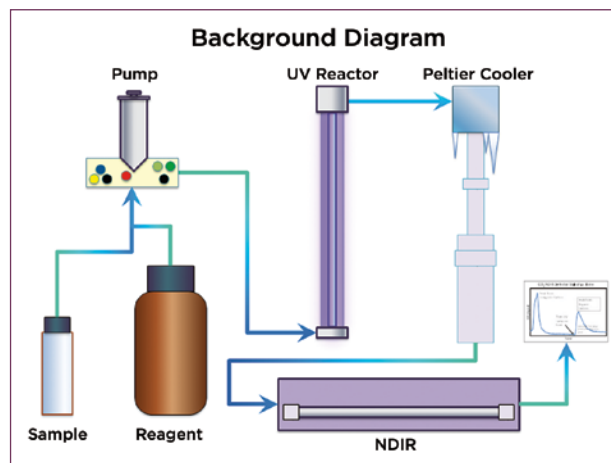
Reliable data

- Stop throwing away your first sample. QbD1200 has virtually eliminated sample-to-sample carryover
- Outstanding reproducibility means no more inconsistent data
- Dynamic Endpoint Detection provides clear assurance of:
 - Complete oxidation of organics
 - Complete removal of inorganic carbon
- No additional inorganic carbon removal module required
- Digital 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 100ppm



Total Organic Carbon

Total organic carbon 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 uses a proprietary technology that oxidizes the organic carbon in to carbon dioxide which is measured to determine the organic carbon concentration. The new QbD1200 strictly adheres to the regulatory requirement of discriminating between inorganic carbon and the organic carbon.



Simplify your validation and analysis

- Unbox your QbD1200 and have it up and running in less than an hour
- No external PC required means no extra Computer System Validation for 21 CFR 11 Compliance
- Large 10.4 inch color touch screen 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
- Low Reagent cost

Fast Calibration

- Automated calibration in approximately 90 minutes

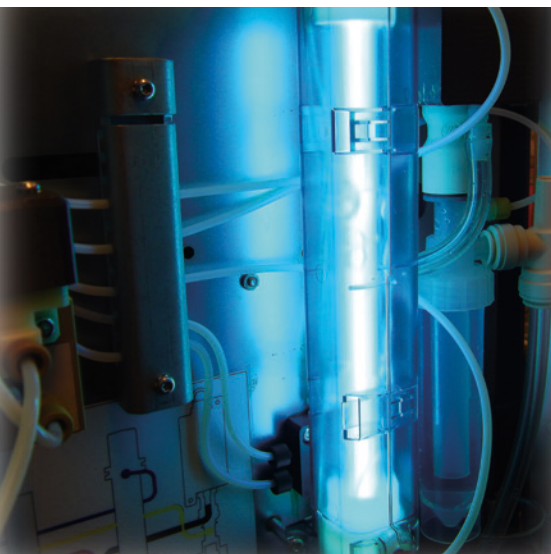
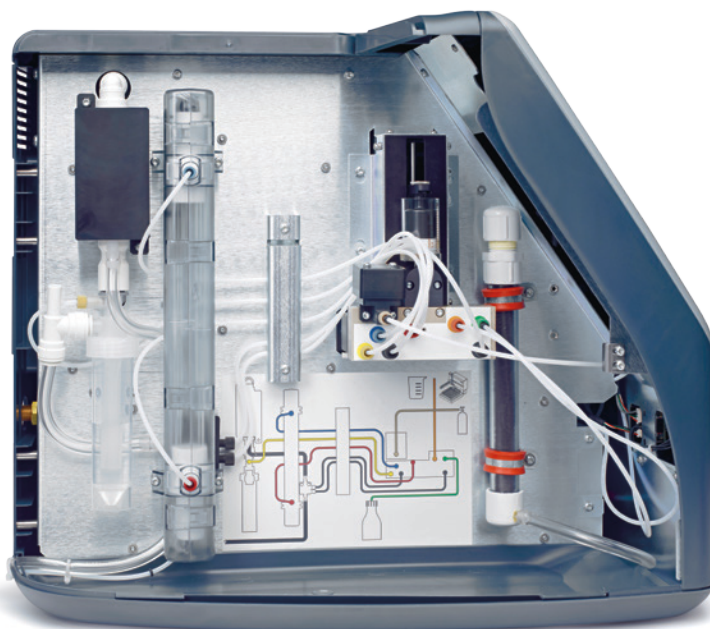
Unexpected, over-ranging samples are no problem for the QbD1200

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



Quality by design approach

- 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 7 sensors at 10 points in the instrument
- Communicates proper functioning of all sub-systems ensuring reliable measurement and providing confidence in the test

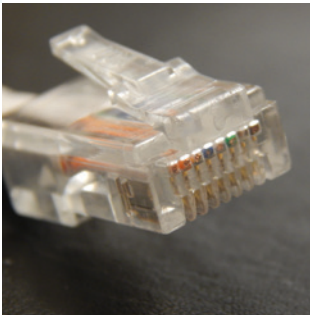


Ensure regulatory compliance with QbD1200

- 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 for 21 CFR part 11 compliance
- Simply paperless feature allows export of data via FTP over secure ethernet
- Send data and reports to a single location for centralized record keeping
- Integrated hard drive encrypts all data with ample storage for 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	90 minutes
Analysis Time	~5 minutes
Sample-to-sample Carryover (from 500 ppb to blank)	< 0.2%
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 assure complete Inorganic Carbon removal?	YES

Instrument Self-Diagnostics to Ensure Data Integrity	
Will Instrument 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 Confirmation	Broadband silicate 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 Confirmation	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	Secure FTP over Ethernet
IO	5 USB, 1 Ethernet
Data Export Formats	PDF, CSV

User Interface	
Display	10.4 inch Hi-Res color touch screen
External PC	No external hardware / PC required
External keyboard / mouse	Optional, not required
Ease of Operation	Intuitive user interface, guides operator through measure setup

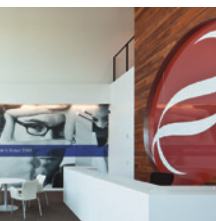
Qualification Routines	
Calibration	Automated routine: 18 point calibration using KHP (6 concentrations, 3 replicates each)
Calibration Standard	5ppm KHP (single 125mL bottle), diluted to achieve 1, 2, 3, 4, 5 ppm concentrations; reagent is used as blank
Verification Tests / System Suitability	Automated routines: <ul style="list-style-type: none"> • USP SST Bulk Water (blank, 500ppb as C: sucrose, benzoquinone) • USP SST Sterile Water (blank, 8ppm as C: sucrose, benzoquinone) • JP-16 <2.59> validation (blank, 500ppb as Carbon SDBS)

Regulatory Compliance	
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 IQ / OQ

Autosampler	
Capacity	64 sample vials (standard 40mL 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
Power	100-240 VAC, 47-63 Hz
Weight	10 kg (22 lbs)
Auto sampler dimensions	W 366 x D 537 x H 457 mm
Power	100-240 VAC, 47-63 Hz
Weight	21 kg (45 lbs)
Operating temperature & humidity	10-35°C; up to 90% relative humidity, non-condensing
Reporting units	µg/L (ppb)

In the interest of improving and updating its equipment, Hach Company reserves the right to alter specifications to equipment at any time.



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