

# BECKMAN COULTER QbD1200

## Total Organic Carbon Analyzer

*Critical Measurements Made Simple*



## Reliable TOC measurements

- ❖ *Stop throwing away your first rep. QbD1200 has virtually eliminated sample-to-sample carryover*
- ❖ *No more inconsistent results, QbD1200 has outstanding reproducibility*
- ❖ *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*

## Simplify your validation and analysis

- ❖ *Get your QbD1200 out of the box and running measurements in less than an hour*
- ❖ *No external PC required, thus 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; enjoy annual service vs. monthly.*
- ❖ *Low Reagent cost*

### **Fast Calibration**

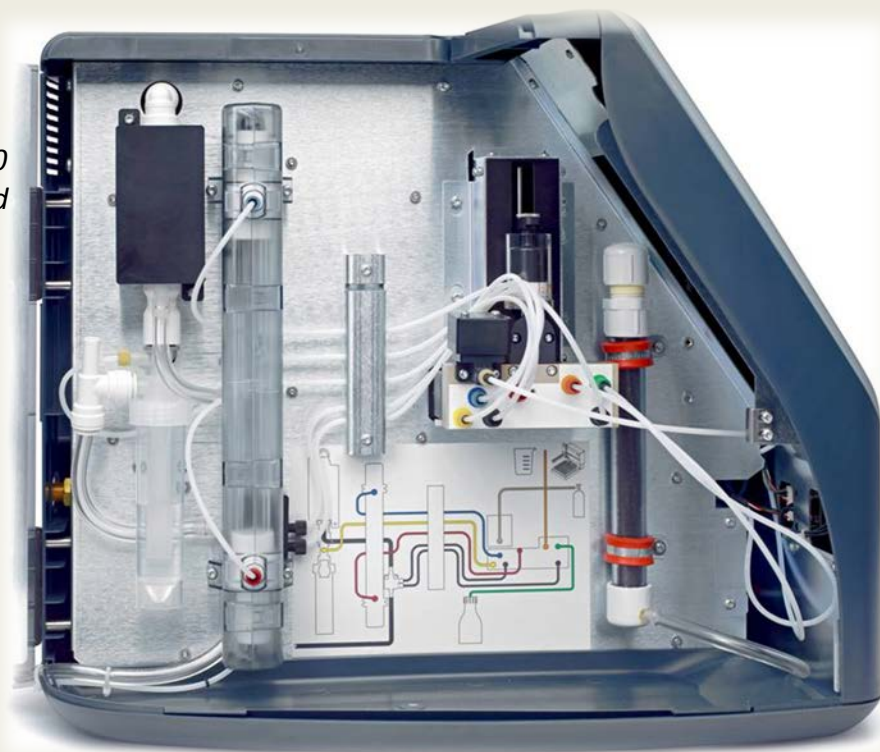
- ❖ *Automated calibration in less than 90 minutes*

### **Unexpected, over-ranging sample? No problem for 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*

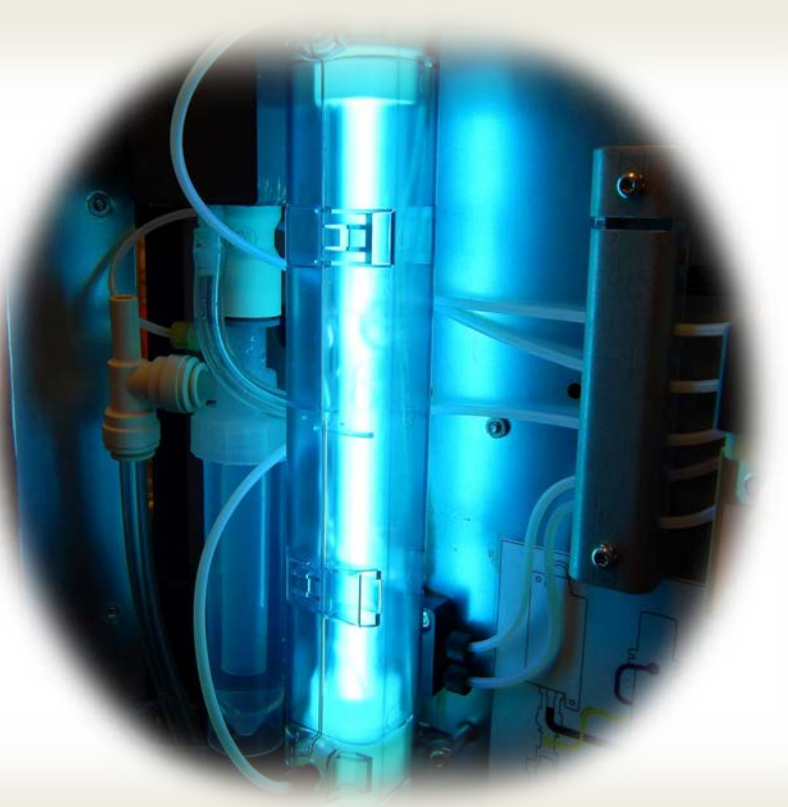
### **Quality by Design approach**

- ❖ *Self-health check runs each time QbD1200 is powered on and available upon demand*
- ❖ *7 sensor types at 10 different monitoring sites continuously check pressure, liquid flow, gas flow, UV lamp intensity, temperature and NDIR detector*
- ❖ *Easily provides confidence that all sub-systems are functioning properly to ensure a reliable measurement*



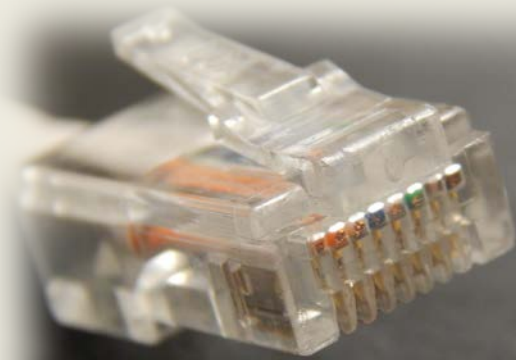
## **Ensure Regulatory Compliance with QbD1200**

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



## **Secure Data**

- ❖ *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*



## Beckman Coulter QbD1200 Laboratory TOC Analyzer



<b>Performance</b>	
Range	0.4 ppb – 100,000 ppb
Detection Limit	0.4ppb
Precision	<2% or 3ppb (whichever is greater)
Accuracy	± 2%
Calibration time	90 minutes
Analysis time	~5 minutes
Sample-to-sample Carryover (from 500ppb to blank)	< 0.2%
Overload Recovery (from 1,000ppm to 1ppm)	1 measurement

<b>Inorganic Carbon Handling</b>	
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

<b>Instrument Self-Diagnostics to Ensure Data Integrity</b>	
<b>Will Instrument report TOC value <u>IF</u>:</b>	
Lamp intensity too low	NO
Carrier gas insufficient / tank runs out	NO
Reagent insufficient / bottle empty	NO
Sample volume insufficient / vial empty	NO

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

<b>Measurement Method and Assurance</b>	
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 <sub>2</sub> free Air, O <sub>2</sub> , or N <sub>2</sub>
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)

<b>Data Storage and Retrieval</b>	
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

<b>User Interface</b>	
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 measurement setup

<b>Qualification Routines</b>	
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	<u>Automated routines:</u> •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)

<b>Regulatory Compliance</b>	
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

<b>Autosampler</b>	
Capacity	64 sample vials (standard 40mL glass TOC vials)
Style	XYZ, septum piercing
Sample tray material	Anodized Aluminum

<b>General Technical Data</b>	
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)