U1600-L

Laboratory TOC Analyzer

Operation, Installation & Maintenance Manual

Document No.	BD-U1600L-MAN-EN	**Revision**	B - Customer release
Release date	4 August 2026	**Language**	English

Customer publication

1. Document Control and Specification Authority

This manual provides the customer operating, installation, calibration, maintenance and qualification guidance for the Blue Dragon U1600-L Laboratory TOC Analyzer. The exact delivered configuration is governed by the document hierarchy below.

1.1 Specification Hierarchy

Priority	Controlling document	Use
1	Serial-number-specific nameplate, order confirmation, packing list, factory test report and calibration certificate	These documents govern the exact delivered hardware, voltage, interfaces, accessories and approved performance.
2	Approved model-specific technical datasheet and written Blue Dragon technical clarification	These documents govern the current standard model specification and supersede earlier general literature.
3	This customer manual	This manual governs standard installation, operation, maintenance and qualification guidance.
4	Interface screenshots and general illustrations	These support operation and component identification. The delivered software version and arrangement take precedence.

RULE	When values differ, use the highest-priority document. Do not change an approved method, range, connection or software setting without documented change control.

1.2 Adopted Model Specification

This release adopts the current Blue Dragon laboratory configuration: 1-1600 µg/L range, 1 µg/L detection limit and resolution, ±3% accuracy, approximately 3-minute analysis and 370 × 350 × 220 mm dimensions. These values supersede earlier general literature that listed different accuracy, analysis time or dimensions.

Field	Details
Product	Blue Dragon U1600-L Laboratory TOC Analyzer
Document	Operation, Installation & Maintenance Manual
Document number	BD-U1600L-MAN-EN
Revision	B - Customer release
Release date	4 August 2026
Language	English
Product family	Blue Dragon Water Quality & Organic Carbon Series
Warranty	12 months, subject to the sales contract
Prepared and issued by	Blue Dragon Technology

1.3 Revision History

Revision	Date	Description	Prepared by
A	4 August 2026	Initial controlled draft based on available operating, technical and qualification documentation.	Blue Dragon Technology

Revision	Date	Description	Prepared by
B	4 August 2026	Customer release: corrected product image; documented specification hierarchy; restored detailed operation and maintenance; expanded model-specific installation, software, data integrity, calibration and qualification; added packing, warranty, spares, options and engineering appendices.	Blue Dragon Technology

1.4 Document Approval

Role	Name / organization	Signature	Date
Prepared by	Blue Dragon Technology		4 August 2026
Technical review			
Quality / document release			

CONTROLLED DOCUMENT	The electronic master issued by Blue Dragon Technology is the controlled copy. Printed or locally saved copies must be checked against the current revision before use.

ILLUSTRATIONS	Product images, interface screens and general-arrangement drawings are representative of the Blue Dragon configuration. The delivered enclosure, software build and serial-specific drawings govern exact appearance and connection location.

Contents

2. Safety Information

Only trained personnel familiar with laboratory electrical equipment, high-purity-water sampling and the site quality system may install, operate or service the analyzer.

2.1 Signal Words

Signal	Meaning
DANGER	Immediate hazard that can result in death or serious injury.
WARNING	Potential hazard that can result in serious injury or major equipment damage.
CAUTION	Potential hazard that can result in minor injury, contamination or equipment damage.
NOTICE	Important operating, quality or data-integrity information.

2.2 General Safety Requirements

- Read this manual before applying power or connecting a sample.
- Use a reliably grounded Class I power supply that matches the delivered nameplate.
- Disconnect and isolate electrical power before opening a service panel or replacing a fuse, UV lamp or pump tube.
- Do not modify internal wiring, fluidics, firmware or software configuration without Blue Dragon authorization and documented change control.
- Inspect the inlet, internal fluid path and drain for leakage during initial operation and after maintenance.
- Use a particle filter of 60 µm or smaller when visible insoluble particles may be present.
- Flush the analyzer after an over-range, contaminated or unsuitable sample before returning to low-level TOC measurement.
- Do not use the analyzer in an explosive atmosphere or where strongly corrosive vapours, condensation or conductive dust may be present.

2.3 Laboratory Sample Safety

- Use only non-pressurized sample containers at the laboratory inlet.
- Use clean, compatible containers and tubing to avoid sample contamination.
- Position the inlet tube securely to prevent spills and loss of prime.
- Handle standards according to their safety data sheets and the site chemical-hygiene plan.

ELECTRICAL	After switching the analyzer off, wait at least 3 minutes before switching it on again.

3. Product Description and Applications

The U1600-L is a compact benchtop total organic carbon analyzer for offline quality-control and laboratory testing of purified water, Water for Injection, ultrapure water, deionized water and cleaning-validation samples. It draws sample from a non-pressurized container and provides touchscreen operation, electronic records and integrated report printing.

Figure 3-1. Blue Dragon U1600-L Laboratory TOC Analyzer.

3.1 Intended Applications

- Offline testing of Purified Water and Water for Injection.
- Pharmaceutical QC, investigation and release-support testing.
- Cleaning-validation rinse samples within the approved range.
- Electronic-grade ultrapure water and deionized water.
- Approved environmental, food and related low-conductivity-water applications.

3.2 Key Features

- Compact benchtop design with 7-inch colour touchscreen.
- Integrated printer and English report output.
- UV oxidation with differential conductivity detection.
- 1-1600 ppb range, approximately 3-minute analysis and ≤3% repeatability.
- 16 GB storage and more than 1,000,000 records.
- RS232, RS485 and USB interfaces.
- Three-level user access, audit trail and electronic-signature functions.
- No routine carrier gas, acid or oxidant.

3.3 Limitations

- The conductivity-based method is intended for low-conductivity, high-purity-water matrices.
- Do not apply the analyzer to wastewater, concentrated process streams, high-salt matrices, suspensions or samples outside the approved range without application review.
- TOC does not replace microbiological, endotoxin or other required pharmaceutical-water tests.
- The user remains responsible for method suitability, sampling representativeness, validation, data review and compliance with the current applicable pharmacopoeia.

4. Measurement Principle

The analyzer uses ultraviolet oxidation with differential conductivity detection. The sample is divided into two matched flow paths. The unoxidized path measures total inorganic carbon (TIC). The oxidized path passes through a

titanium-dioxide photocatalytic reactor illuminated by a dual-wavelength 185 nm and 254 nm UV lamp and measures total carbon (TC).

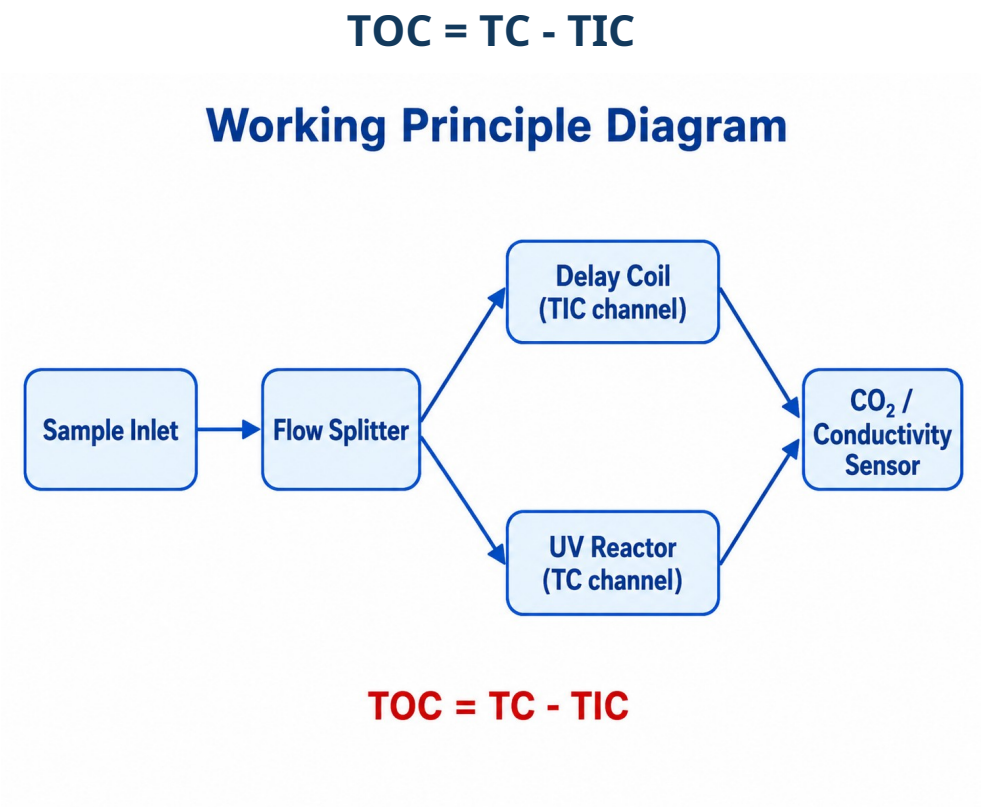


Figure 4-1. TOC measurement flow path and calculation principle.

4.1 Analytical Sequence

1. The sample enters the analyzer and is divided into matched TIC and TC paths.
2. The TIC path passes through a delay coil and conductivity/temperature sensing channel without UV oxidation.
3. The TC path passes through the UV photocatalytic reactor, converting oxidizable organic carbon to carbon dioxide.
4. The conductivity response of both channels is temperature compensated.
5. The controller calculates TOC from the difference between TC and TIC and stores the result with associated metadata.

4.2 UV Reactor

The reactor uses a spiral quartz flow path around a 185/254 nm UV lamp. UV intensity declines with operating time; oxidation efficiency must be maintained through service-life monitoring, system suitability and scheduled lamp replacement.

4.3 Measurement Units

For water, 1 µg/L carbon is numerically equivalent to 1 ppb carbon. Results may be displayed in µg/L, ppb or mg/L according to software configuration. Low-level pharmaceutical-water results should normally be reviewed in µg/L or ppb to avoid unit-conversion errors.

5. Technical Specifications

The table below is the approved customer-release specification for the standard U1600-L. The order confirmation, nameplate, factory test report and calibration certificate govern the serial number.

Parameter	Approved standard specification
Measurement range	0.001-1.6000 mg/L carbon (1-1600 µg/L; 1-1600 ppb).
Detection limit	0.001 mg/L (1 µg/L; 1 ppb).

Parameter	Approved standard specification
Resolution	0.001 mg/L (1 µg/L; 1 ppb).
Accuracy	±3%.
Repeatability	≤3%.
Analysis time	Approximately 3 minutes per test.
Testing principle	UV oxidation + differential conductivity detection.
Conductivity range	0-10 µS/cm.
Sample temperature	1-70 °C.
Sample source	Non-pressurized sample bottle or container.
Recommended sample volume	At least 300 mL for routine operation unless the approved method states otherwise.
Storage	16 GB; more than 1,000,000 records.
Interfaces	RS232, RS485 and USB.
Display	7-inch colour touchscreen.
Print output	Integrated English report printing.
Power	220 VAC; confirm nameplate voltage and frequency.
Dimensions	370 × 350 × 220 mm.
Operating environment	10-40 °C; RH ≤85%; avoid condensation.
Calibration interval	Recommended at least annually or according to the approved site program.
Compliance support	USP <643>, current Ph. Eur. 2.2.44, applicable ChP requirements and FDA 21 CFR Part 11-supporting functions.
Data integrity	Three-level access, audit trail and electronic signatures standard; database / app functions depend on configured options.

5.1 Performance Interpretation

- Detection limit and display resolution are different parameters. A displayed decimal place does not establish validated quantitation below the detection limit.
- Accuracy and repeatability apply under approved calibration, sample and environmental conditions.
- Analysis time is the nominal test duration; stabilization, washing and response time may extend the time before a reportable result is obtained.
- Communication protocols, report format, language and optional software functions depend on the delivered configuration.

CONTROL	The factory test report and calibration certificate supplied with the serial number govern the released performance configuration.

6. Receiving, Packing and Storage

6.1 Receiving Inspection

1. Inspect the shipping container for impact, puncture, moisture or mishandling before opening.
2. Photograph and document any visible shipping damage before removing the analyzer.
3. Verify the model, serial number, voltage and ordered options against the order confirmation and packing list.
4. Inspect the enclosure, touchscreen, fittings, tubing, printer or print interface and accessories.
5. Retain the original packaging until installation, commissioning and initial performance verification are complete.

6.2 Unpacking

- Remove transit restraints and protective foam before powering the analyzer.
- Do not lift the analyzer by the touchscreen, fittings, fans, tubing or printer opening.
- Allow the analyzer to reach room temperature before powering it if it has been transported through cold or humid conditions.

6.3 Storage and Transportation

Condition	Requirement
Storage location	Indoor, cool, clean and well ventilated; no corrosive gas.
Storage relative humidity	Not greater than 80%; prevent condensation.
Transportation	Use the original packaging where possible; protect against impact, vibration and moisture.
Reinstallation	Perform under controlled service procedures and repeat applicable IQ/OQ checks.

RETURN	Before returning an analyzer, obtain service authorization, decontaminate the fluid path, drain all liquid and package the unit in suitable protective materials.

7. Installation and Connections

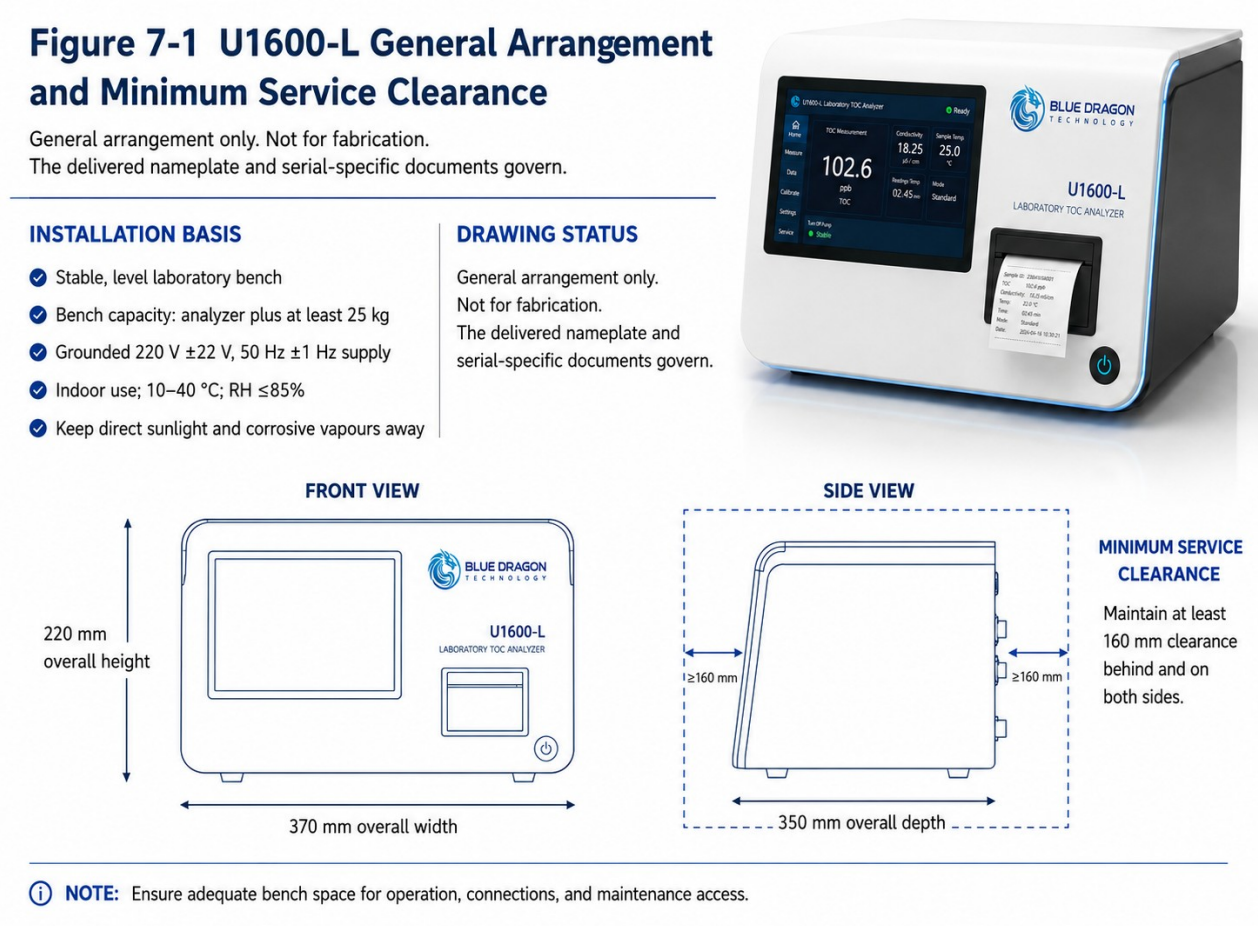


Figure 7-1. U1600-L general arrangement and minimum service clearance.

7.1 Laboratory Location

- Place the analyzer on a clean, stable, level and unobstructed bench.
- The bench must support the analyzer plus at least 25 kg additional load.

- Maintain at least 160 mm clearance behind and on both sides for ventilation and service.
- Avoid direct sunlight, strong vibration, electromagnetic interference, corrosive vapours and condensation.
- Operating environment: 10-40 °C, relative humidity ≤85%, with daily temperature change within ±5 °C where possible.

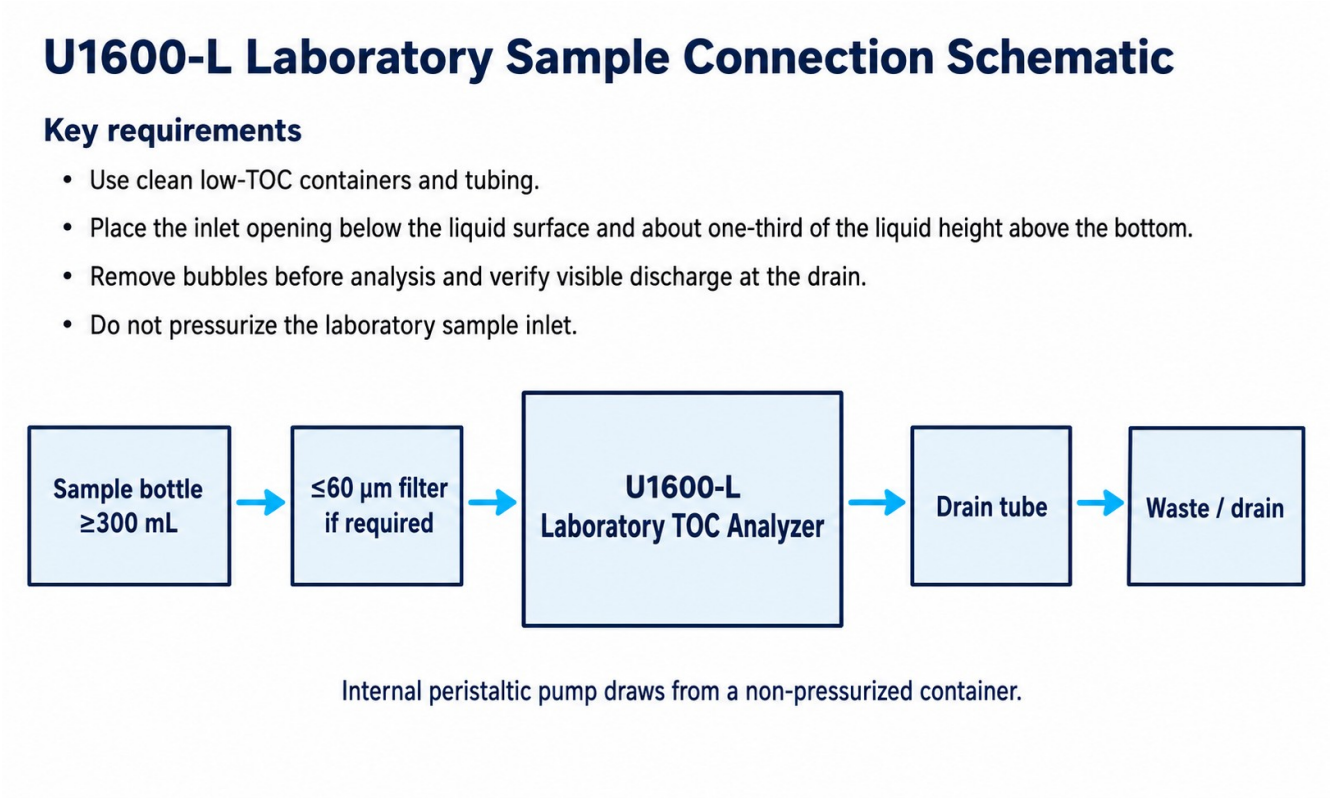


Figure 7-2. U1600-L laboratory sample and drain connection.

7.2 Sample and Drain Connections

Item	Requirement
Sample source	Clean, non-pressurized bottle or container; prepare at least 300 mL for routine analysis unless the approved method states otherwise.
Inlet tube	Immerse below the liquid surface with the opening approximately one-third of the liquid height above the container bottom.
Particles	Filter through ≤60 µm membrane when visible insoluble particles may be present.
Drain	Route without kinks or restriction to a suitable waste container or drain; verify visible discharge during operation.
Sample temperature	1-70 °C. Allow samples and standards to equilibrate according to the approved method.
Printer	Load approved paper and keep the paper path dry and unobstructed.

7.3 Rear Panel and Power Connection

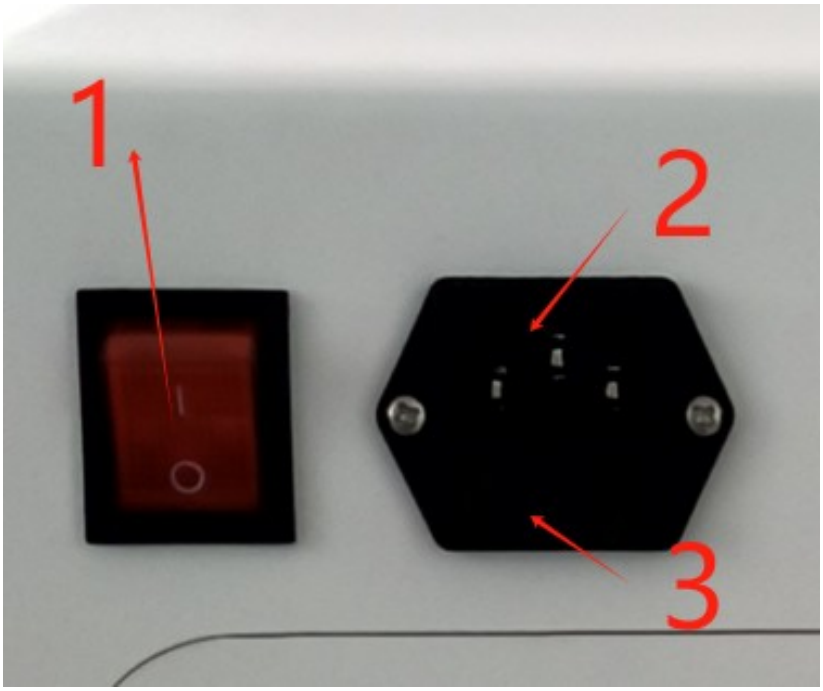


Figure 7-3. Power switch, power inlet and fuse location.

Label	Function
1	Main power switch.
2	Power inlet.
3	Fuse holder.

- Connect to 220 V ±22 V, 50 Hz ±1 Hz, with protective earth.
- Do not replace a fuse until the cause of failure has been investigated. Use only the approved type and rating.

8. Software, Users and Data Integrity

The standard configuration includes multi-level user access, audit-trail and electronic-signature functions intended to support regulated workflows. Compliance depends on validated configuration, approved procedures, network controls, training, periodic review and the user site quality system.

8.1 Login and User Roles

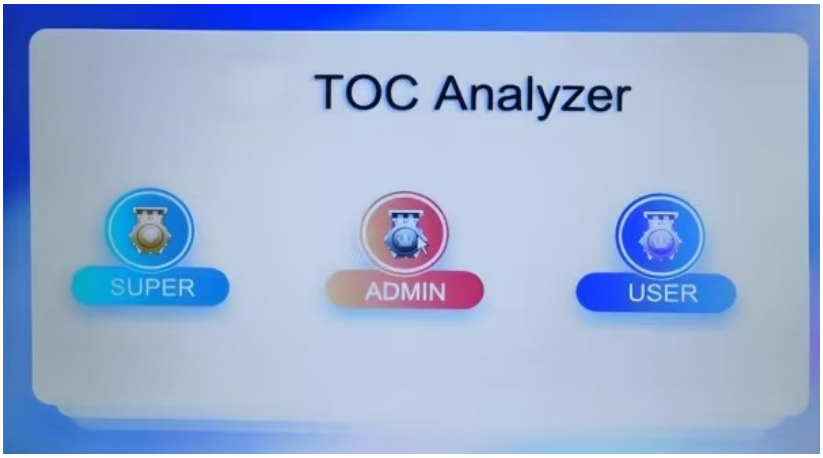


Figure 8-1. User login interface.

Role	Minimum intended authority
Super Administrator	Create and disable accounts; assign permissions; configure date/time, settings, calibration, alarms, export, audit trail and system information.
Administrator	Operate approved settings, cleaning, testing and record review according to assigned permissions.
User / Operator	Routine cleaning and testing only, unless additional rights are approved.

- Assign a unique account to each individual.
- Change the initial password at commissioning.
- Do not use shared administrator accounts for routine operation.
- Disable accounts promptly when access is no longer required.
- Define password length, expiry, failed-login handling and account recovery in the site procedure.

8.2 Menu Structure

Figure 8-2. Main function interface.

8.3 Date and Time

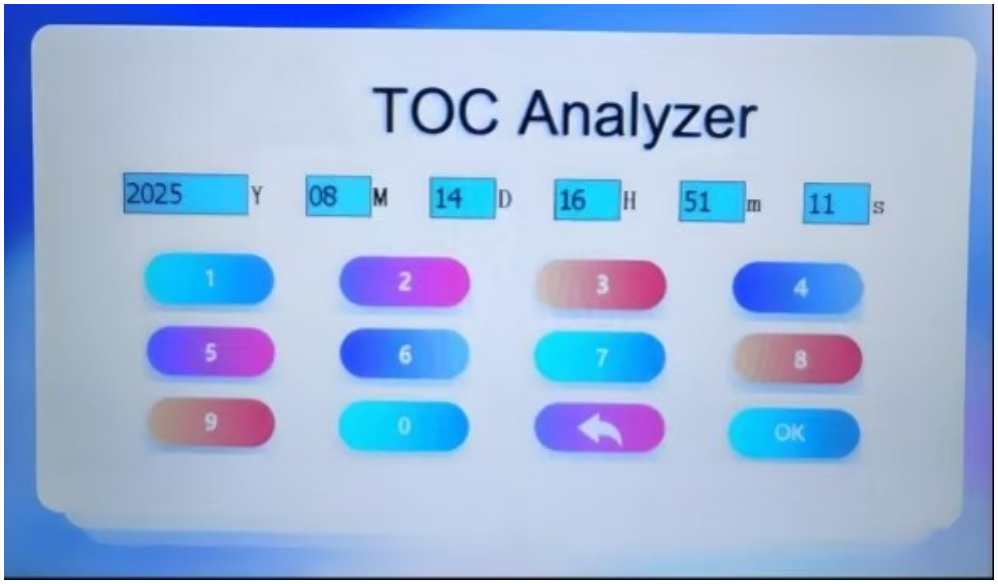


Figure 8-3. Date and time setting interface.

- Set date, time and time zone during IQ.
- Restrict clock changes to authorized administrators.
- Review clock changes in the audit trail.
- Synchronize with the approved site time source where supported.

8.4 Audit Trail and Electronic Signatures

- The audit trail must record user identity, date/time, action and relevant before/after values for critical operations.
- Define which records and events require routine audit-trail review.
- Electronic signatures must be linked to the signed record and have a defined meaning such as performed, reviewed or approved.
- Do not overwrite, obscure or manually alter electronic raw data outside an approved controlled process.
- Record-retention duration must be configured and verified during OQ; do not assume a retention period solely from memory size.

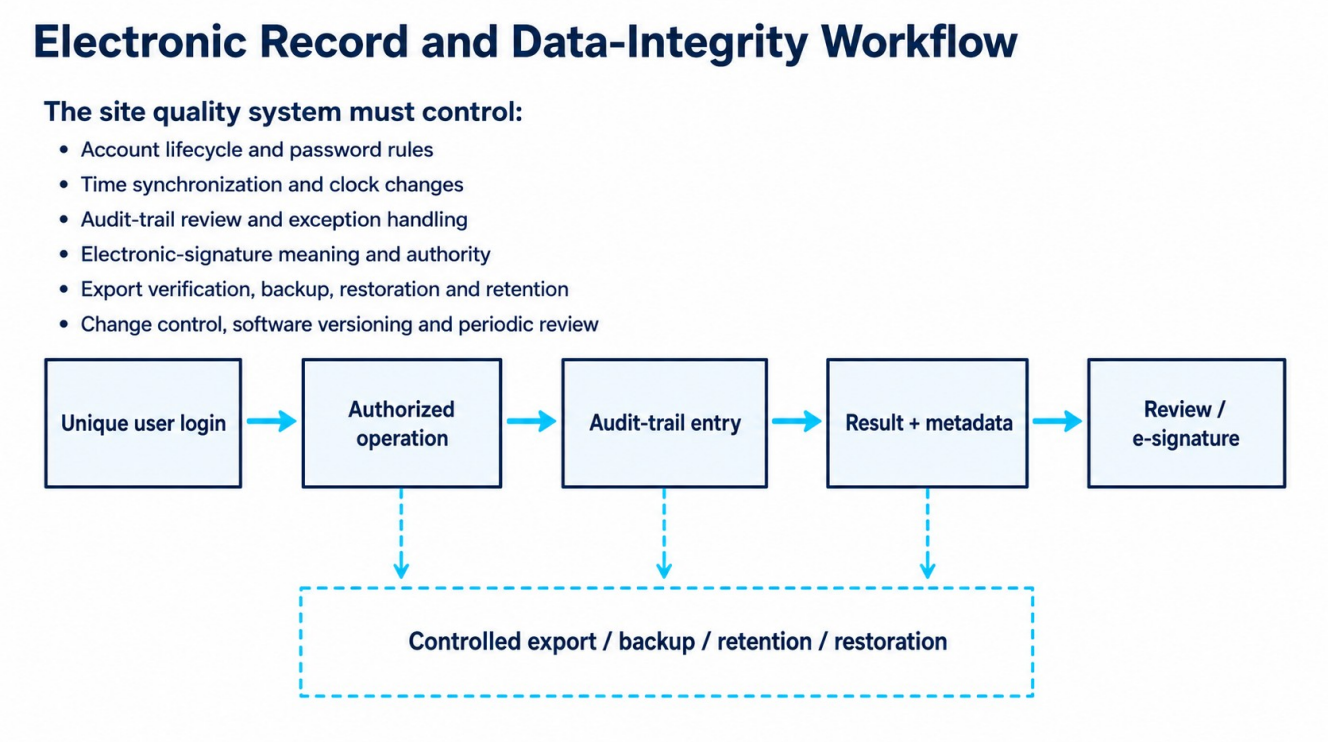


Figure 8-5. Electronic record and data-integrity workflow.

8.5 Export, Backup and Restoration

CRITICAL	Before routine use, OQ must verify whether Export copies records or transfers and clears selected records from local memory. Do not approve routine export until this behaviour, file format, completeness and restoration method are documented.

1. Use only controlled and malware-screened USB media or an approved network destination.
2. Select the required date range and record type.
3. Perform the export and retain the on-screen completion message or audit entry.
4. Open the exported files on an approved system and verify record count, readability, metadata and checksums where available.
5. Confirm whether the records remain accessible on the analyzer.
6. Document backup location, retention, access control and restoration testing.
7. Restart the analyzer after export only when required by the delivered software version and approved procedure.

8.6 Software Change Control

- Record software and firmware versions during IQ.
- Assess upgrades for validation impact before installation.
- Back up data and configuration before authorized updates.
- Repeat affected OQ/PQ tests after changes.
- Maintain a controlled list of interfaces, network settings and report templates.

9. Commissioning and Start-up

9.1 Pre-Power Checklist

Check	Acceptance	Result
Correct model, serial number and voltage verified	Complies with this manual and order documents	☐ Pass ☐ Fail
Transit restraints removed	Complies with this manual and order documents	☐ Pass ☐ Fail
Protective earth connected	Complies with this manual and order documents	☐ Pass ☐ Fail
Inlet and drain correctly routed	Complies with this manual and order documents	☐ Pass ☐ Fail
No visible damage or loose fittings	Complies with this manual and order documents	☐ Pass ☐ Fail
Service clearances available	Complies with this manual and order documents	☐ Pass ☐ Fail
Approved low-TOC water and standards available	Complies with this manual and order documents	☐ Pass ☐ Fail

9.2 Initial Power-up

1. Apply power and confirm normal startup, touchscreen response and absence of abnormal noise.
2. Log in as Super Administrator using the controlled initial credential.
3. Change the initial password and create named user accounts.
4. Set and verify date, time, language, units and report configuration.
5. Record software version, serial number, storage status and interface settings.
6. Configure alarm limits according to the approved application and validation plan.

9.3 Initial Fluid-Path Cleaning

Use ultrapure water or WFI. For first use, alternate forward and reverse washing for 10 minutes in each direction and repeat three cycles. Inspect all connections for leakage and confirm stable discharge without visible bubbles.

CLEANING	If the analyzer has been stored for a long period or exposed to a high-TOC sample, extended cleaning for more than 6 hours may be required.

9.4 Release for Use

1. Complete applicable IQ checks.
2. Perform calibration or verification.
3. Perform system suitability where required.
4. Complete OQ functional tests, including users, audit trail, export, alarms and records.
5. Complete PQ using approved standards and representative samples.
6. Obtain formal QA or authorized release before routine regulated use.

10. Routine Operation

10.1 Prepare the Sample

1. Use a clean low-TOC container and collect a representative sample under the approved sampling procedure.
2. Prepare at least 300 mL unless the validated method requires a different volume.
3. Filter through a 60 µm or smaller membrane only when insoluble particles are present and the filter is approved for TOC use.
4. Rinse or condition the inlet tube with the sample where required.
5. Place the tube opening below the liquid surface and approximately one-third of the liquid height above the bottom.

10.2 Cleaning and Carryover Control

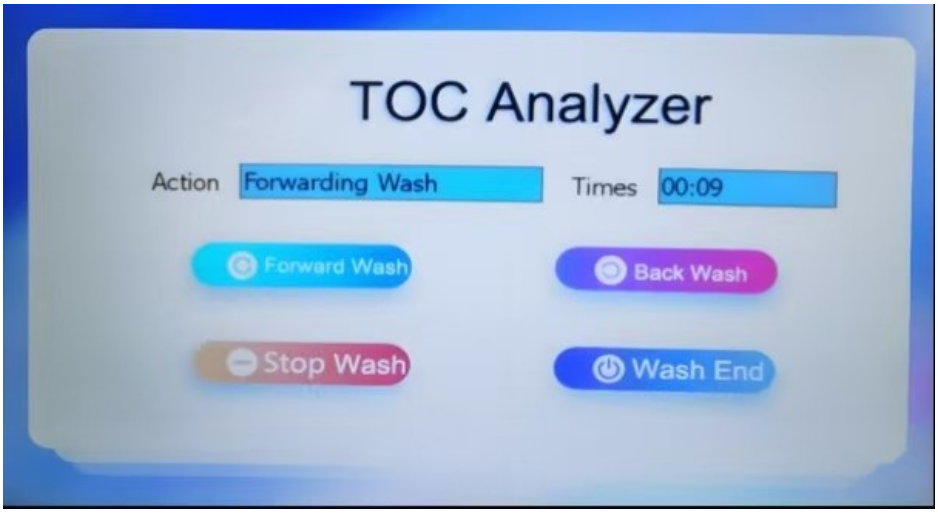


Figure 10-1. Forward and reverse washing interface.

Condition	Required washing sequence
First use	Alternate Forward Wash and Back Wash for 10 minutes each; repeat 3 cycles.
After one week idle	Alternate Forward Wash and Back Wash for 5 minutes each; repeat 2 cycles.
Accidental tap-water or contaminated-water exposure	Alternate Forward Wash and Back Wash for 15 minutes each; repeat 6 cycles.
Between different samples	Back Wash to drain the previous sample; condition with the next sample using Back Wash for 3 minutes and Forward Wash for 3 minutes before testing.
Long-term shutdown	Back Wash with ultrapure water for more than 2 hours, remove the rinse source and continue reverse operation until the fluid path is drained.

Under normal conditions, wash for 30-60 minutes. If the analyzer has been unused for a long time or has measured high-TOC water, cleaning for more than 6 hours may be required.

10.3 Run a Test

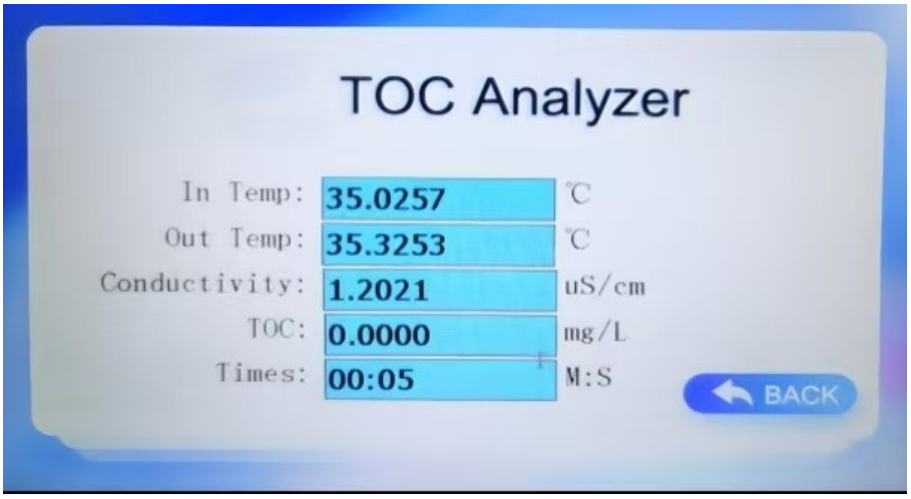


Figure 10-2. Laboratory analysis interface.

1. Confirm stable power, clean fluidics, correct date/time and approved user login.
2. Connect the inlet and drain and verify flow without leakage or bubbles.
3. Select Test and enter sample identification where available.
4. Allow the full analysis cycle to complete without moving the tube or disturbing the sample.
5. Review TOC, conductivity, temperature, units, status and any alarm.

6. Print or export the result according to the approved procedure.
7. Wash the analyzer before the next sample or shutdown.

10.4 Historical Records

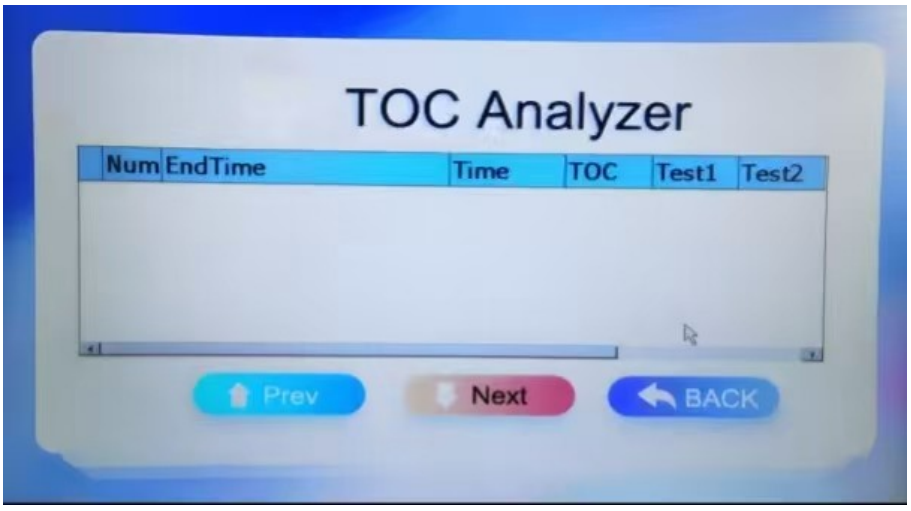


Figure 10-3. Historical-record interface.

Select Historical Data to review stored records. Use Prev and Next to navigate. Where printing is enabled, select the required record for report output. Confirm the record identity and unit before use in a quality decision.

10.6 Routine Operating Precautions

- Remove all visible bubbles before accepting results.
- Verify normal drain discharge throughout operation.
- Do not allow inlet or drain tubing to kink, flatten or become submerged at the outlet.
- Keep tubing immersed in clean low-TOC water during short idle periods where the approved procedure requires it.
- Seal exposed tube ends during extended idle periods to prevent contamination.
- Wait at least 3 minutes after shutdown before restarting.

11. Calibration, Verification and System Suitability

11.1 Calibration Control

Use traceable standards, approved containers and the delivered calibration procedure. The recommended calibration interval is at least annually, or more frequently when required by the site quality system, instrument performance, maintenance, relocation or investigation.

1. Verify instrument cleanliness, stable flow, correct units and current UV-lamp service status.
2. Confirm standard identity, lot, expiry, storage, preparation and traceability.
3. Wash with low-TOC water until the blank is stable.
4. Open the Calibration function using an authorized account.
5. Run the approved blank and calibration standard sequence.
6. Review replicate agreement and acceptance criteria before saving the calibration.
7. Run an independent verification standard or system-suitability sequence.
8. Review the calibration audit trail and approve the record under the site procedure.

CALIBRATION	Do not adjust calibration solely to force agreement with an expected result. Investigate contamination, bubbles, flow, temperature, expired standards and UV performance first.

11.2 USP <643> / Pharmacopoeial System Suitability

Where required, use TOC water, sucrose reference standard and 1,4-benzoquinone reference standard prepared or supplied under the applicable current pharmacopoeia. The supplied qualification framework uses 500 µg/L carbon sucrose and 500 µg/L carbon 1,4-benzoquinone solutions.

$$\text{Response efficiency (\%)} = 100 \times (Rss - Rw) / (Rs - Rw)$$

Symbol	Meaning
Rw	Response to TOC water / reagent-water blank.
Rs	Response to sucrose reference solution.
Rss	Response to 1,4-benzoquinone reference solution.

Acceptance for response efficiency is 85-115%. For the pharmaceutical-water test, compare the sample response corrected for the blank with the applicable limit response defined by the current pharmacopoeia and approved site method. Do not substitute an unverified display value for the pharmacopoeial response calculation.

11.3 Repeatability and Performance Verification

Test	Recommended customer-release acceptance
Blank stability	Meets the approved method and does not compromise the limit response.
Repeatability	≤3% under the approved instrument performance test unless a separately approved method defines a different calculation.
Accuracy / verification	Within ±3% for the approved verification condition or within the acceptance stated on the factory method.
Response efficiency	85-115%.
Carryover	Returns to the approved blank after the validated wash sequence.

11.4 Failed Calibration or System Suitability

1. Place affected results on hold back to the last successful verification as required by the site risk assessment.
2. Check standard preparation, blank water, containers, units, flow, temperature, bubbles and maintenance status.
3. Clean the analyzer and repeat the test with fresh approved standards.
4. Inspect or replace the UV lamp if oxidation efficiency remains low.
5. Document the investigation, corrective action, impact assessment and authorized release.

12. Maintenance

12.1 Preventive-Maintenance Schedule

Interval	Task
Before use / daily	Inspect tubing, fittings, drain, enclosure and touchscreen; verify no leaks, kinks or bubbles.
Weekly	Review blank trend, alarms, storage capacity and critical audit events; inspect filter condition.
Monthly	Inspect cables, ground, fans/ventilation, printer or print interface, data backup and system clock.
6 months continuous service	Replace the dual-wavelength UV lamp or assess extension under an approved risk-based program.
12 months	Replace peristaltic-pump tubing; perform calibration, preventive maintenance and applicable OQ/PQ checks.
After relocation or major repair	Repeat installation checks, leak test, calibration and affected qualification tests.

12.2 Fluid-Path Care

- Use only approved low-TOC rinse water.
- Never use abrasive tools in the fluid path.
- Remove bubbles by washing until the transparent section is bubble free.
- If no liquid discharges, inspect the filter and tubing; a small clean syringe may be used by trained personnel to draw from the outlet and restore flow.
- After a contaminated or over-range sample, extend cleaning before low-level analysis.

12.3 UV Lamp Replacement

WARNING	Disconnect the power cord before opening the rear cover. The UV lamp and quartz reactor are fragile. Wear clean gloves and eye protection.

1. Turn off the main power switch, unplug the power cord and wait at least 3 minutes.
2. Remove the rear-cover screws and open the service panel.
3. Disconnect the UV-lamp power plug.
4. Loosen the lamp-holder lock nut and slowly withdraw the lamp without contacting or stressing the surrounding spiral quartz tube.
5. Handle the new lamp with clean gloves. Remove accidental fingerprints from the lamp or quartz surface with suitable ethanol and a lint-free wipe.
6. Insert the new lamp, position it correctly in the reactor and tighten the lock nut without overtightening.
7. Reconnect the lamp power plug and reinstall the service panel.
8. Reset or record the lamp service time, clean the fluid path, calibrate or verify the analyzer and complete system suitability as required.

12.4 Peristaltic-Pump Tube Replacement

SERVICE	This procedure is for trained service personnel. Confirm the replacement tube and internal arrangement against the serial-number-specific service information.

1. Turn off and unplug the analyzer; wait at least 3 minutes.
2. Open the rear service panel and identify the pump tube, pressure ring, pressing block and spacer block.
3. Loosen the hex screws at both ends of the pump pressure ring and then loosen the pump-tube pressing block.
4. Remove the tube from the pump ring and disconnect its ends from the conductivity-sensor outlet and waste line.
5. Transfer or install the spacer block on the approved replacement tube at the same position.
6. Place the middle section of the new tube in the pump ring and tighten the pressure-ring screws evenly.
7. Secure the tube ends in the pressing and fixing blocks and reconnect the sensor outlet and waste line.
8. Reinstall the cover, connect low-TOC water, leak-test, verify stable flow and repeat calibration or verification as required.

12.5 Fuse Replacement

1. Disconnect power and investigate the cause of the blown fuse.
2. Open the fuse holder at the power inlet.
3. Install only the same approved type and rating stated on the delivered nameplate or service documentation.
4. Close the holder, reconnect power and verify normal startup.
5. If the replacement fuse fails, disconnect the analyzer and contact Blue Dragon Technical Support.

12.6 Printer Paper

- Use the approved paper roll and load it with the printable side correctly oriented.
- Do not pull paper backwards through the mechanism.
- Keep the printer dry and remove paper dust during preventive maintenance.

- Verify printed units, date/time and sample identification after loading.

12.7 Maintenance Release

After any maintenance affecting the fluid path, measurement system, software or records, document the work, parts used and test results. Complete leak testing, cleaning, calibration and the affected OQ/PQ checks before returning the analyzer to regulated use.

13. Troubleshooting

Symptom	Probable cause	Corrective action
No display after power-on	Fuse failed; loose power connection; incorrect supply	Disconnect power; verify supply and cord; replace fuse only with approved type; contact support if fault repeats.
Unstable or excessive error	Bubbles; kinked/flattened tubing; unstable flow; contamination	Inspect tubing and drain; remove bubbles; wash with low-TOC water; verify flow and sample conditions.
Result much lower than expected	UV lamp aged or oxidation efficiency poor	Review lamp service time; run system suitability; replace lamp and recalibrate if required.
High blank or carryover	Contaminated water, container or fluid path	Use fresh TOC water and clean containers; perform extended forward/reverse washing.
No drain discharge	Blockage; pump tube worn; drain backpressure	Inspect filter/tubing; remove kinks; use approved syringe method; replace pump tube; ensure open drain.
Touchscreen or button not responding	Software state; damaged control; liquid ingress	Restart under approved procedure; keep interface dry; contact service if fault persists.
Buzzer or alarm	TOC exceeds limit; flow/temperature issue; internal fault	Review alarm message and sample source; verify flow/temperature; follow deviation procedure; contact support for persistent internal alarm.
Historical query freezes	Printer configured but unavailable; storage or software issue	Connect/configure printer as supplied; restart under approved procedure; verify storage and software version.
Export incomplete or records unavailable	Media, permissions, storage or export mode	Stop use of export; preserve audit trail; verify media and file count; restore from backup or contact support.
System suitability fails	Standards, blank, contamination, flow, calibration or UV issue	Repeat with fresh traceable standards after cleaning; verify flow and units; inspect lamp; document investigation.

ESCALATION	Record the model, serial number, software version, symptom, alarm text, sample conditions, recent maintenance and steps already taken before contacting support.

14. U1600-L Qualification Requirements

The qualification plan supplied with the analyzer is a framework and must be approved and adapted by the user quality unit. The requirements below separate the laboratory and online configurations so that installation, function and performance are verified against the actual use.

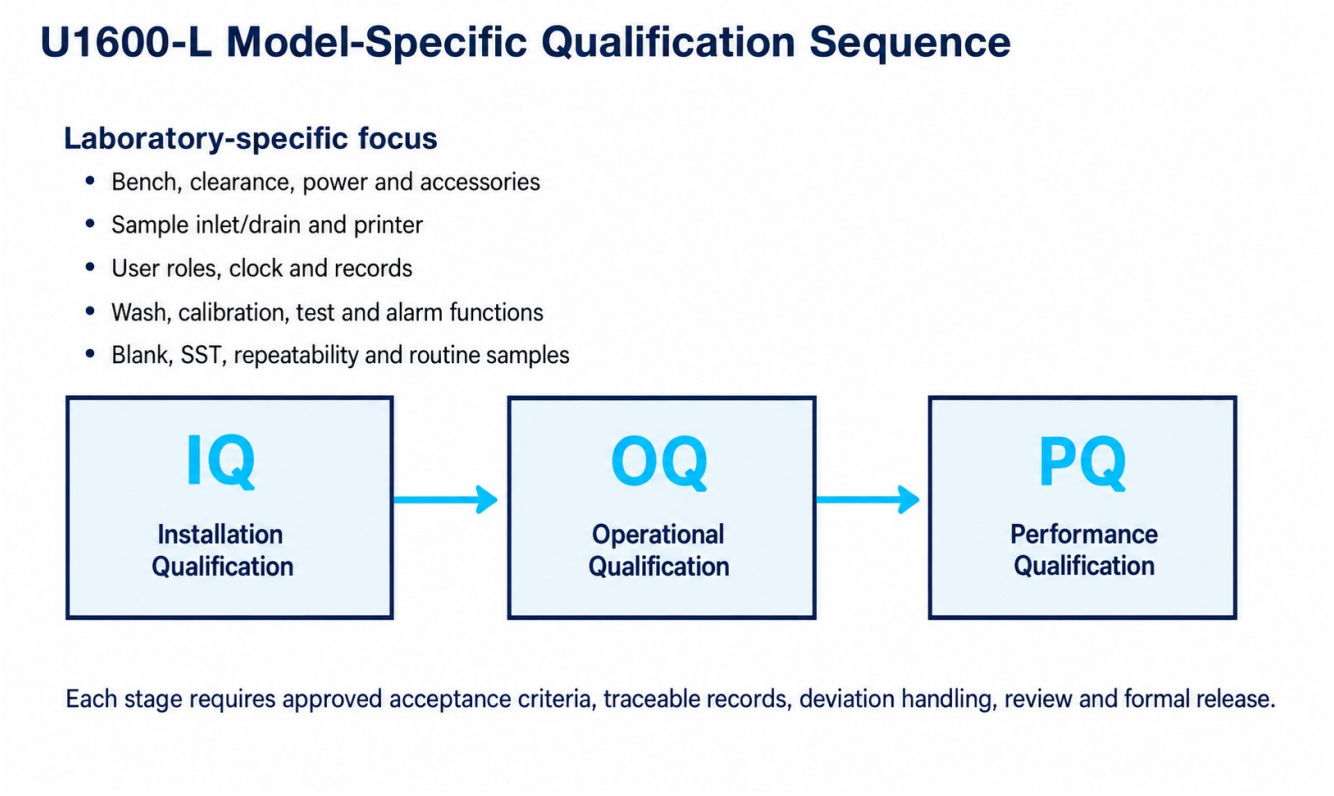


Figure 14-1. U1600-L model-specific qualification sequence.

14.1 Installation Qualification (IQ)

IQ item	Acceptance requirement
Documentation	Manual, packing list, certificate, calibration data, software version and ordered options are present and controlled.
Instrument identity	Model U1600-L, serial number, voltage and nameplate match the order.
Bench and clearance	Stable level bench supports analyzer plus 25 kg; 160 mm rear/side clearance.
Environment	10-40 °C, RH ≤85%, no condensation, corrosive vapour or direct sunlight.
Sample and drain	Non-pressurized inlet, clean tubing, unrestricted drain and ≥300 mL sample capacity.
Printer / accessories	Printer paper, stylus where supplied, fuse, tubing and power cord present.
Electrical / interfaces	Grounded power and RS232/RS485/USB configuration recorded.
Software / users	Version, user roles, clock, storage and report settings documented.

14.2 Operational Qualification (OQ)

OQ item	Acceptance requirement
Power-up and self-test	Starts normally without abnormal noise or leakage.
Touchscreen / printer	Controls respond and reports print with correct units and metadata.
Forward / reverse wash	Both directions operate and remove bubbles.
Calibration function	Authorized calibration sequence operates and records the event.
Test function	Sample can be drawn, analysed, stored and printed.
Historical data	Records can be searched and reported with correct metadata.

OQ item	Acceptance requirement
Users / audit trail	Permissions, critical events and electronic signatures meet the approved matrix.
Alarm	Upper-limit alarm and any configured output operate.
Export / backup	Copy/transfer behaviour, record count, readability, local retention and restoration are verified.

14.3 Performance Qualification (PQ)

PQ item	Acceptance requirement
Blank / baseline	Stable low-TOC blank meets the approved method.
System suitability	Sucrose / 1,4-benzoquinone response efficiency 85-115%.
Repeatability	≤3% under approved performance-test conditions.
Verification / accuracy	Within ±3% for the approved verification condition.
Carryover	Approved wash returns the analyzer to the defined blank after a challenge sample.
Representative samples	Purified water, WFI or approved cleaning-validation samples meet predefined comparison and precision criteria.

14.4 Deviations and Release

- Document all deviations, investigation, impact, corrective action and retest.
- Do not release the analyzer while critical IQ/OQ/PQ failures remain open.
- The quality unit or authorized approver must sign the completed qualification and define requalification triggers.
- Typical triggers include relocation, major repair, lamp/reactor replacement where required by risk assessment, software upgrade, data-integrity configuration change and repeated performance failure.

15. Warranty and Technical Support

15.1 Standard Warranty

The standard warranty is 12 months unless the sales contract states otherwise. Warranty service covers defects in supplied materials and workmanship under approved installation, operation and maintenance conditions.

15.2 Warranty Exclusions

- Unauthorized repair, modification or software change.
- Incorrect or unstable power, inadequate grounding or electrical surge.
- Operation outside approved sample, pressure, temperature, humidity or environmental limits.
- Blocked tubing, drain backpressure, unsuitable samples or incompatible cleaning materials.
- Use of non-approved lamps, tubing, fuses, standards or accessories.
- Damage caused by transport, impact, liquid ingress, corrosion, misuse or failure to follow maintenance requirements.
- Normal consumable wear.

15.3 Information Required for Support

Information	Where to obtain it
Model and serial number	Nameplate and Device Information screen.
Software / firmware version	Device Information screen.
Alarm or symptom	Screen message, audit trail and operator observation.

Information	Where to obtain it
Sample conditions	Source, TOC range, conductivity, temperature, pressure and flow.
Recent work	Maintenance, calibration, standards and parts used.
Evidence	Photographs, exported records, trend, log and qualification status.

Support organization	Blue Dragon Technology
Website	bluedragontechnology.com
Product	U1600-L Laboratory TOC Analyzer
Document	BD-U1600L-MAN-EN

16. Shutdown, Storage and Disposal

16.1 Routine Shutdown

1. Complete the current test and confirm records are stored.
2. Export or back up records according to the approved procedure.
3. Wash with approved low-TOC water.
4. Use reverse operation to drain the fluid path where the approved procedure requires it.
5. Return to the main screen, switch off and disconnect power.

16.2 Extended Storage

- Clean and drain the internal fluid path.
- Seal tube ends and ports against dust and contamination.
- Store in a cool, clean, ventilated indoor location without corrosive gas and with RH ≤80%.
- Retain configuration, maintenance, backup and shutdown records.
- On return to service, repeat initial cleaning, calibration and the qualification tests required by the risk assessment.

16.3 Disposal

Dispose of the UV lamp, electronic assemblies, batteries where present, pump tubing, filters, standards and contaminated waste according to local regulations and site procedures. Remove or securely erase regulated electronic records before disposal or transfer of ownership.

Appendix A. Standard Supply and Packing List

Item	Typical quantity	Notes
U1600-L main unit	1	Benchtop analyzer with printer.
Power cord	1	Voltage as ordered.
Inlet tube	1 length	For non-pressurized sample container.
Drain tube	1 length	Route to suitable waste.
Fuse	1	Approved rating.
User manual	1	Electronic or printed copy.
Certificate of Conformity	1	Order-specific document.
Warranty documentation	1	As supplied.

Item	Typical quantity	Notes
Printing paper	1 roll	Approved printer paper.
Stylus	1	Where supplied.

PACKING	The delivered packing list and order confirmation govern. Report shortages or shipping damage before installation.

Appendix B. Consumables and Recommended Spare Parts

Item	Reference / interval	Recommended stock	Notes
Dual-wavelength UV lamp	Ref. 19058Z / about 6 months	1	Confirm against serial number.
Peristaltic-pump tubing	Ref. 10062Z / about 12 months	1 set	Approved material and size.
Fuse	Nameplate rating	2	Use identical approved type.
Printer paper	Order-specific	2 rolls	Keep clean and dry.
Inlet / drain tubing	Order-specific	1 set	Maintain cleanliness and compatibility.
Particle filters	≤60 µm / application-dependent	As required	Low-TOC compatible.
Calibration / SST kit	Within expiry	1 active set	TOC water, sucrose and 1,4-benzoquinone standards.

Confirm all part numbers against the serial number before ordering. Store UV lamps in protective packaging and keep tubing, filters and standards clean and within stated shelf life.

Appendix C. Options and Accessories

Option	Purpose	Order / validation note
Database package	Expanded data management and database functions.	Validate retention, access, backup and restoration.
Custom app / remote package	Remote review and reporting.	Validate network and record functions before regulated use.
External data-integration kit	RS232/RS485 interface to site systems.	Protocol and mapping are order-specific.
Standards kit	Calibration and pharmacopoeial system-suitability standards.	Use within expiry and approved storage conditions.
IQ/OQ/PQ support	Document package and execution assistance.	Adapt and approve under the site quality system.
Annual service kit	UV lamp, pump tubing and selected spares.	Confirm serial-number compatibility.

Appendix D. Software and Data-Integrity Checklist

Control	Status	Evidence / reference
Unique named accounts configured	☐ Yes ☐ No	
Initial passwords changed	☐ Yes ☐ No	
Roles and permissions approved	☐ Yes ☐ No	

Control	Status	Evidence / reference
Date/time and time zone verified	☐ Yes ☐ No	
Clock changes recorded in audit trail	☐ Yes ☐ No	
Audit trail records critical actions	☐ Yes ☐ No	
Electronic-signature meaning defined	☐ Yes ☐ No	
Export copy/transfer behaviour verified	☐ Yes ☐ No	
Export completeness and readability verified	☐ Yes ☐ No	
Backup location and retention approved	☐ Yes ☐ No	
Restoration test completed	☐ Yes ☐ No	
Software version and interfaces recorded	☐ Yes ☐ No	
Network/cybersecurity review completed	☐ Yes ☐ No	
Periodic audit-trail review frequency defined	☐ Yes ☐ No	

Appendix E. Qualification Forms

E.1 Qualification Approval

Role	Name	Signature	Date
Protocol prepared by			
Engineering review			
QC review			
Quality approval			

E.2 System Suitability Record

Field	Record
Instrument model / serial	
TOC water lot / expiry	
Sucrose standard lot / expiry	
1,4-Benzoquinone standard lot / expiry	
Rw	
Rs	
Rss	
Response efficiency (%)	
Acceptance: 85-115%	☐ Pass ☐ Fail

Field	Record
Performed by / date	
Reviewed by / date	

E.3 Deviation Record

Field	Entry
Deviation number	
Qualification stage	☐ IQ ☐ OQ ☐ PQ
Description	
Immediate action	
Root cause	
Impact assessment	
Corrective action	
Retest result	
Approval / date	

Appendix F. Engineering Drawings and Connection Schematics

Figure 7-1 U1600-L General Arrangement and Minimum Service Clearance

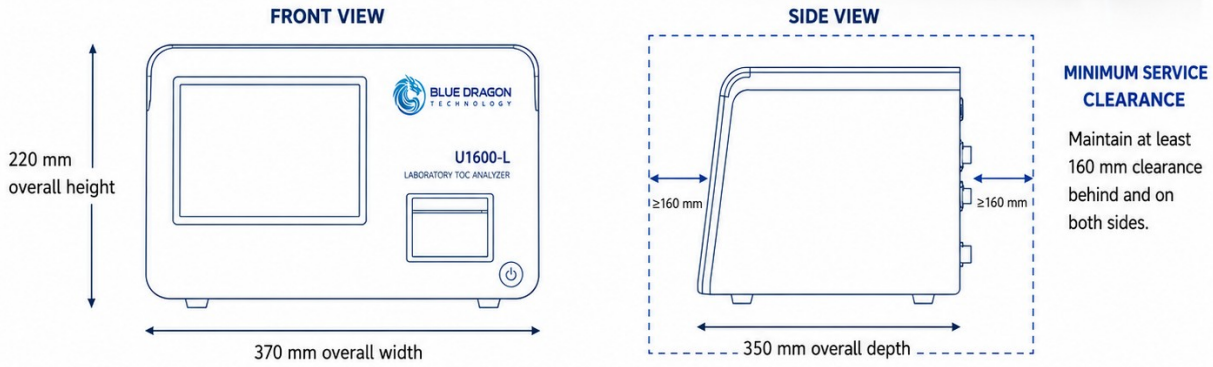
General arrangement only. Not for fabrication.
The delivered nameplate and serial-specific documents govern.

INSTALLATION BASIS

- Stable, level laboratory bench
- Bench capacity: analyzer plus at least 25 kg
- Grounded 220 V ±22 V, 50 Hz ±1 Hz supply
- Indoor use; 10–40 °C; RH ≤85%
- Keep direct sunlight and corrosive vapours away

DRAWING STATUS

General arrangement only.
Not for fabrication.
The delivered nameplate and serial-specific documents govern.



MINIMUM SERVICE CLEARANCE

Maintain at least 160 mm clearance behind and on both sides.

NOTE: Ensure adequate bench space for operation, connections, and maintenance access.

Drawing F-1. U1600-L overall dimensions and service clearance.

U1600-L Laboratory Sample Connection Schematic

Key requirements

- Use clean low-TOC containers and tubing.
- Place the inlet opening below the liquid surface and about one-third of the liquid height above the bottom.
- Remove bubbles before analysis and verify visible discharge at the drain.
- Do not pressurize the laboratory sample inlet.

Internal peristaltic pump draws from a non-pressurized container.

Drawing F-2. U1600-L laboratory sample and drain arrangement.

Drawing item	Controlled value
Overall dimensions	370 W × 350 D × 220 H mm.
Bench clearance	At least 160 mm behind and on both sides.
Bench capacity	Analyzer plus at least 25 kg additional load.
Sample connection	Non-pressurized inlet tube from clean sample container.
Minimum sample volume	300 mL for routine test unless method specifies otherwise.
Drain	Unrestricted tube to suitable waste.

DRAWING STATUS	General-arrangement drawings are not for fabrication. The mounting template, nameplate and serial-number-specific drawings supplied with the analyzer take precedence.

Appendix G. Maintenance and Calibration Records

G.1 Maintenance Log

Date	Operating hours / use	Maintenance or inspection	Parts used	Verification result	Performed by

G.2 Calibration / Verification Log

Date	Standard / lot	Expected	Measured	Acceptance	Operator	Reviewer

G.3 UV Lamp and Pump Tube Record

Date	Component	Part number	Service hours	Post-maintenance check	Performed by

End of Manual

BLUE DRAGON TECHNOLOGY

U1600-L Laboratory TOC Analyzer
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