

SWAN BIOTECH PVT. LTD.

QUALITY SOLUTIONS



Product Brochure

Water Quality Solutions

Clean Room Solutions

Bio-decontamination

**GLOBAL
PARTNERS**



TOC Analyzer



- Shimadzu's TOC Analyzer is the World leader in the analysis of carbon species in water (TOC).
- Based on 680°C Catalytic Combustion aided Oxidation/NDIR Detector.
- Used for analysis of TOC in water, which contain hard-to-decompose insoluble and macromolecular organic compounds.
- Passed the TOC Oxidation performance evaluation test (EU Standards EN 1484 Annexure C) with 99.4% recovery.
- Meets or exceeds the requirement of USP/EP/JP for PW & WFI water.
- Fully compliant with 21 CFR Part 11 Compliance.

“USP 643 : For PW & WFI water.”

“Validation of purification system”

“Cleaning Validation”

“Measurement of TN in Protein”

“USP 661.1 : Plastic materials for construction”

“USP 661.2 : Plastic Packaging Systems for Pharmaceutical Use”

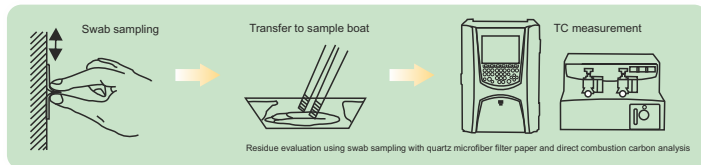


OCT-L

TOC-L

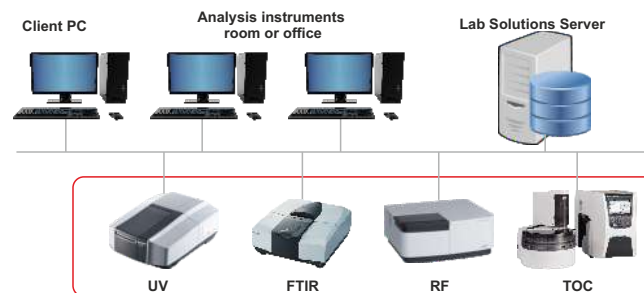
ASI-L

Swab Sampling/Direct Combustion



- Carbon-free quartz fiber swab
- Pretreated at >600°C for 15 min
- To be wetted with 0.5 mL of purewater before swabbing

Lab Solutions Connectivity



Online TOC Analyzer

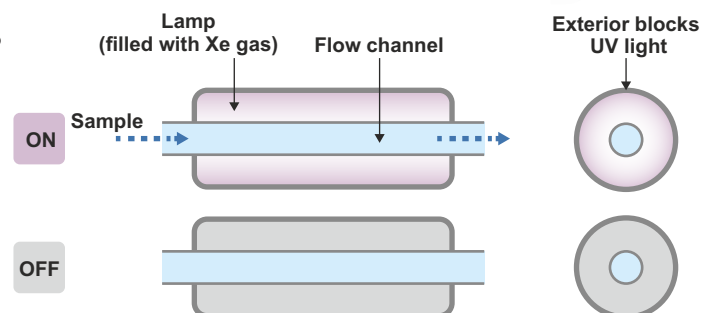
First TOC analyzer in the world to use a mercury-free excimer lamp.
New “Active-Path” technology for transferring energy from the lamp to the sample



- Shimadzu eTOC has very high sensitivity & low detection limits, reaching 0.1 µg/L, perfectly suitable for ultra-pure water measurement.
- Excimer lamps emit high-energy 172 nm wavelength light by inducing a dielectric barrier discharge within a xenon gas.
- Efficiently irradiates the sample inside the lamp with ultraviolet light to reliably oxidize organic matter.



- Meets regulations in major pharmacopeias viz., USP, EP, IP & JP
- Large indicator and display on a small cabinet
- Small, lightweight casing provides installation flexibility
- Onsite calibration/validation using a vial sampler and Conditioned standard solutions are also available
- Export data in an easily readable/usable format
- Fully 21 CFR Part 11 compliance
- Lab Solutions Compatibility
- Security functionality for supporting data management



Microbial Air Sampler

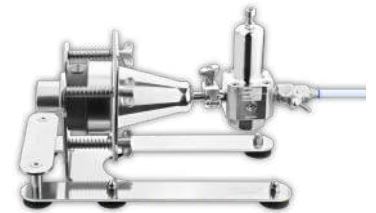


- Technopolymer body shock proof with anti bacterial performance of surface (Body & Polymer).
- Quick bayonet closure.
- Volume of aspirating air : 100 / 180 / 200 LPM.
- Memorized data : 1000 samplings.
- Calibration reminder.
- Delayed , remote, start, simultaneous or interval sampling.
- 100 configurable user and places.
- Programmable for compressed gas / air.
- Data integrity 21 CFR part 11 compliance.
- The data are transferred via Bluetooth.



Microbial Air Sampler for Compressed / Nitrogen Air

- A stainless steel calibrated valve guarantees 100 LPM flow rate.
- Each component of the TRIO.GAS adaptor instrument is autoclavable.
- When TRIO.GAS is used in combination with a TRIO.BAS air sampler the time is regulated by the software of the air sampler.
- All the sampling data are transferred via Bluetooth.



ASPI GAS CHAMBER

- Simultaneous measurements of 6 particle sizes viz., 0.3µm, 0.5µm, 1.0µm, 3.0µm, 5.0µm, 10.0µm.
- Small footprint.
- Stainless steel enclosure.
- Available in 100, 50.0, 28.3LPM flow rates.
- Complies with all requirements of ISO21501-4.
- Large touch screen displays all measurements.
- Stores upto 10,000 measurements.



Portable Particle Counter

- Laser Particle sensor with integrated pump.
- Compact stainless steel enclosure with sensors.
- Multi parameter measurements: Particle count, Air velocity, Temp., RH, DP.
- Multi function, user friendly monitoring software.
- Alarms: Warning light, On-screen / Pager notice.

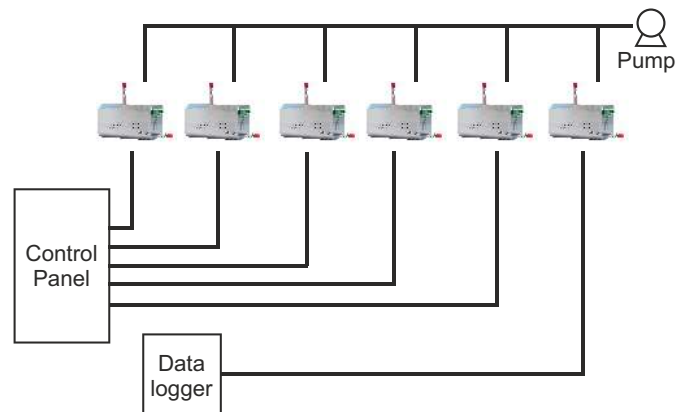


Particle Counter for Clean Rooms



Particle Counters & Sensors

- 2 channel remote Light scattering particle sensor.
- 1.0cfm flow rate (28.3LPM).
- Analog output for easy integration with existing systems.
- 0.3 to 0.5 micron sensitivity.
- Compact body with stainless steel enclosure.



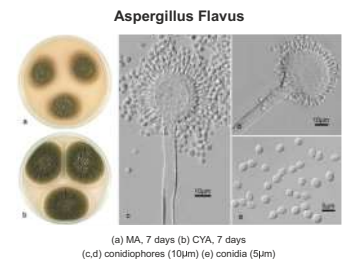
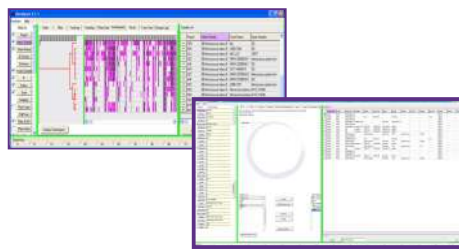
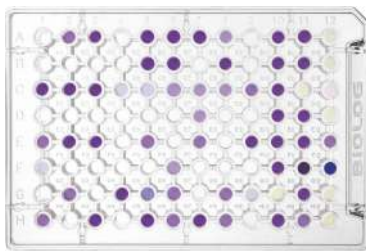
Microbial Identification Systems



ABILITY TO IDENTIFY FUNGI

World leader in
Cell-based
Phenotypic Identification

- Identification based on carbon utilization & biochemical reaction (71 Carbon Source + 23 Biochemical).
- Database specifically designed for Industrial and environmental.
- Identify over 2,900 species of aerobic and AN Bacteria, YT, FF.
- Meets 21 CFR part 11 compliance.
- User domain access feasible.



Aspergillus Flavus
(a) MA, 7 days (b) CYA, 7 days
(c,d) conidiophores (10µm) (e) conidia (5µm)

- Gram stain and other post-tests not needed.
- Single Microplate covers entire GP & GN aerobic bacteria.
- 1500 Aerobic database
- Trending & Tracking
- Data management
- Dendrogram
- Customized database
- Ability to Identify Fungi
- Micro & Macroscopic images available.
- 710 FF database



Isolate



Prepare



Inoculate



Incubate & Read

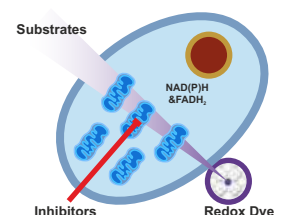
Phenotype Micro Array Technology

- Enables researchers to evaluate nearly 2000 phenotypes of a microbial cell in a single experiment.
- Analyzes thousands of cellular phenotypes under thousands of culture conditions in a simple, rapid, cost effective assay.



Mitochondrial Assays

- Analyze Mitochondria at Higher Resolution
- 96 assays in one experiment
- Colorimetric electron flow readout
- MitoPlate S-1 : 31 Substrates
- MitoPlate I-1 : 22 Inhibitors
- Permeabilize cells and feed substrates or inhibitors directly to the mitochondria



Rapid Sterility Test System



- PROMICOL's, growth based Rapid Sterility Testing technology reduced sterility testing time to 48-72 hours instead of traditional 14 days.
- Rapid sterility is alternative test method to USP 71, EP 2.6.1 and JP 4.06 sterility tests which allows for shorter incubation periods and faster results.
- Microbial contamination detection based on the presence of microbial Adenosine Triphosphate (ATP) in a sample.
- ATP-bioluminescence is a global FDA & EMA approved and well-established method.
- PROMICOL's Solution fits for both the methods:
 - Filterable Samples (Membrane Filtration Sterility Testing).
 - Non Filterable Samples (Direct Transfer Sterility Testing).
- Benefits:
 - Faster release of drug product.
 - Implementing Corrective action sooner if the product does not meet specifications.
 - Allows for microbial ID to support OOS investigations.



Water Activity (ERH) Meter



Lab model



Temperature Controlled

- High precision/resolution measurement for water activity/Equilibrium relative humidity (ERH)
- Alternative test to microbial limit test as per USP for non sterile pharmaceutical dosage, forms like API's, Formulations (Creams, Ointments, Lotions, Liquids) etc.
- Meets or exceeds the requirements of USP-NF 1112, <922>, <1115>.
- Digital Sensor Technology.
- Easy to operate Non-destructive measurement.
- International certified calibration standards available.
- Absolutely no maintenance and no recurring cost.
- Suitable for laboratory and Production site/on-site monitoring applications.
- Sorption Isotherm can be generated for the measurement of moisture content.
- HW4 is a user-friendly PC software to configure, securely record and report Rotronic measuring instruments' values.
- 21 CFR Part 11 Compliant

Rotronic RH and Temperature Dataloggers



Mapping data logger



RH & Temp Transmitter



Transit data Logger



RH & Temp Calibrator

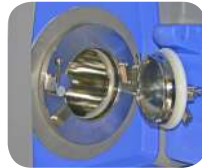


CRP5

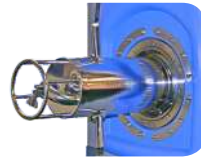
Sterility Test Isolator



- Fully validated sterility test Isolator with built-in bio decontamination system
- Designed as per GAMP5, cGMP, PDA & FDA requirements
- High level and effective bio-decontamination validated @ 6-log sporicidal reduction.
- In-built bio-decon sterility testing isolator.
- ISO 5/Grade A Environment generated in the chamber with laminar air flow @ 0.35m/s to maintain aseptic conditions.
- The fastest bio-decontamination cycle in the market.
- Integrated environmental monitoring system.
- Used for Cell therapy and compounding of various pharma ingredients.
- Fully 21 CFR part 11 compliant.
- RTP port available.



Alpha port



SS Beta Container



Multi chamber isolator

Qube: External Dimensions

	Width (mm)	Depth (mm)	Height (mm)
QHPV/QEXT	1360	843	2335
QMTD	660	800	1750

Qube: Internal Dimensions

	Width (mm)	Depth (mm)	Height (mm)
QHPV/QEXT	1100	540	750
QMTD	440	365	495

RTP Port Dimensions

	Width (mm)	Length (mm)
RTP	190 or 270	NA
Beta Container	190 or 270	400 or 520



BQ "Triple-Lock" Assurance (Biological Indicator/Chemical Indicator/H₂O₂ Solution)



BI

H₂O₂

CI

- BQ BIs, CIs and peroxide engineered to work together with BQ equipment
- Achieve robust, rapid, repeatable, optimal bio-decon cycles
- Customer support/ expertise from one organisation
- Simplified supply chain

Hydrogen peroxide Vapour (HPV) Generator



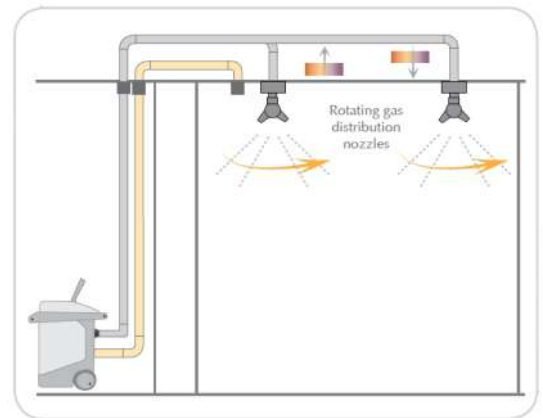
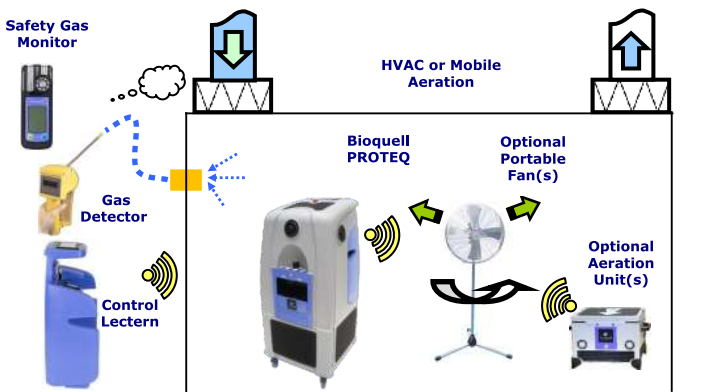
- Hydrogen peroxide vapour (HPV) bio-decontamination technology, capable of 6-log sporicidal reduction.
- High capacity fixed, mobile or semi-permanent configuration for enclosures and rooms up to 500m³.
- Fast, Validatable bio-decontamination cycles.
- Excellent material compatibility including sensitive electronics/PCB's/Panels.
- Effective for wide range of micro-organisms.
- Meets the requirement of cGLP, & cGMP regulatory.
- Fully 21 CFR part 11 compliant.



L4



ProteQ



Cart to Cart / Walk In Chamber



Pass Through Chamber



Walk-In Chamber

- HPV enabled material transfer chamber incorporating a pre-integrated and optimized H₂O₂ vapour for safe movement of material
- Zone to Zone transfer facility through an interlocked bio-decontamination process
- While transferring, it eliminates the transfer of contamination on the surface of materials and equipment.
- Integrated catalyst for fast decontamination cycles from 35-45 minutes
- It prevents cross contamination/spread of infection with an automated process including safety interlocking.
- Various types of modules based on user selective size, C2C-600, C2C-900 & Walk-In-Chamber (WIC).



Control Unit

Dual Bottle Module

H2O2 Vaporizer

Internal Dimensions	
Pass Through Chamber	700 x 700 x 700 mm
Walk-In Chamber	1500 x 2200 x 2500 mm

High Quality Water Purification System



- Generates three qualities of water independently from tap water: Ultrapure Water (Type I), Purified water (Type II) and Osmotized Water (Type III).
- Meets USP and ASTM standards.
- Displays Resistivity, Conductivity and Temperature of Water Inlet and outlet parameters.
- Continuous, Volume & Time control modes of water dispensing.
- Automation of Instrument warns about the change of consumables as well as abnormalities such as inlet water cut, or malfunction of the measuring sensors.
- Equipment calibrated by certified standard traceable to national standards of German DKD
- Easy to use and maintain system.



WFI & Pure Steam Generator



- For regular production of WFI distillate and condensed Pure Steam.
- COMBI units for simultaneous production of WFI & Pure Steam (Optional: Customizations).
- Small foot-print, Highest flexibility, Reduced costs of investment, installation, service and validation.
- Proportional regulation of all media for system stability.
- Both steam heated & electrically heated standard unit options, from 25 L/h to 7000 L/h.
- Any time Pure Steam production for autoclave & freeze dryer.
- Automatic switching between WFI and Pure Steam.

Bio Waste Decontamination System



- Patented Batch & Flow Decontamination Systems from 70 l/day to 180,000 l/day
- Pre-engineered units or custom-made solutions.
- Guaranteed thermal decontamination for a safe release of your effluents
- PLC-controlled operations with monitored and recorded cycles.
- Patented heating technologies with energy recovery systems.



KUBE
70 L/d



MICRO
300 L/d



ULTIMATE
15,000 L/d



CYCLOBATCH
1,000 - 14,000 L/d

Head Space Analyser (O₂ & CO₂)



- Headspace oxygen analysis in vials/bottles/sealed containers
- Testing the quality of Nitrogen air cylinders/ Generators
- Easily transported and used at remote locations such as the packaging line
- Suitable for continuous operation in routine QC/QA testing.
- The DualTrak is used for measurement of many types of modified atmosphere (MAP).

Compressed / Nitrogen AQMS



- Based on color change detector tube
- Oil Mist, Water vapor, CO, CO₂, NO + NO₂, H₂S, SO₂
- As per USP - NF 24, EP 4 - 2.1.6, IP - 2.1.1 and BP 2.1 .6



Cleaning Validation Swabs



- Polyester head material
- Chemical resistance & good sorbency
- Autoclave for reuse
- Tested with Textile committee for lint free & non-abrasive

TX 714A

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