

Bioquell® Qube

The ideal isolator with integrated
bio-decontamination

A closed environment with integrated bio-decontamination



Ecolab's Bioquell Qube provides an aseptic ISO 5 / Grade A environment and includes integrated Bioquell Hydrogen Peroxide Vapour technology, achieving a validated 6-log sporicidal kill on every exposed surface within operating areas.

From its polymer moulding to its integration with Bioquell bio-decontamination technology, the Bioquell Qube is truly unique. Users can select from a 2, 4 or 6 glove configuration with up to 2 transfer chambers or rapid transfer ports (RTPs) for transferring materials into and out of the Bioquell Qube. Its design allows for a small footprint with no required construction for installation.

With its standardised design and software, users receive consistent and uniform installation, validation service and support.

Technicians can stay efficient by performing critical tasks in a Grade A/ISO 5 environment while bio-decontaminating incoming supplies in an adjacent chamber in as little as 30 minutes.

In 12 to 16 weeks from order date, a validated and operational system can be installed in your facility without construction, ductwork or additional electrical needs as the system requires only a standard outlet to function.

The Bioquell Qube can be located in a lower grade or Clean Non-Classified (CNC) area and is a key tool to reduce the risks of contamination from operators and environment to critical aseptic processes while promoting regulatory compliance with GMP in mind.

Applications:

- ▼ Sterility testing
- ▼ Small scale filling
- ▼ Cell and gene therapy drug development and manufacturing
- ▼ Pharmacy compounding
- ▼ Cytotoxic drug and sterile preparations (when selecting ducted option)
- ▼ Transfer isolator for large production isolators

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ANNEX 1 COMPLIANT BPR APPROVED

Bioquell HPV-AQ 35%
hydrogen peroxide approval
written into European law -
Biocidal Products Regulation
(BPR, Regulation (EU) 528/2012)



GRADE A / ISO 5 WORKSPACE

Provides a Grade A / ISO 5
closed environment with
sufficient airflow to meet
Annex 1 guidance values



AUTONOMOUS

Runs from a single plug and socket



VALIDATED CYCLE

A residue-free validated 6-log sporicidal
kill achieved on every cycle

The isolator with benefits built In

The Bioquell Qube's easy installation and many operational features provide a high degree of user assurance including:

Traceability

- ▮ Active air sampling and continuous particle monitoring and environmental monitoring options
- ▮ Optional data logging allowing compliance with 21-CFR Part 11
- ▮ Built-in screen and camera to view batch instructions or record actions
- ▮ RFID (Radio Frequency Identification) functionality facilitates key data collection and traceability

Ease of Use

- ▮ Aseptic hold can be retained for up to 7 days based on client process validation
- ▮ Maintain a Grade A/ISO 5 environment while hosted in lower grade areas
- ▮ Validated bio-decontamination cycles based on custom load configurations

Integration

- ▮ Rapid bio-decontamination cycles with integrated Hydrogen Peroxide Vapour technology
- ▮ No construction or electrical work required for installation
- ▮ Symbio Flex Sterility Pump(s) integration option for sterility testing applications
- ▮ Integrated glove integrity testing

Operations

- ▮ Bio-decontaminate incoming materials while working in another chamber
- ▮ One inch tri-clover port in any workspace chamber
- ▮ Racking options and accessories to maximise throughput
- ▮ Optional Rapid Transfer Port (RTP) for aseptic material transfer

Efficacy

- ▮ Easily switch between negative or positive pressure
- ▮ Easy to use touchscreen navigation
- ▮ Ergonomically designed



Polymer design unlocks unique benefits



The Bioquell Qube is the first isolator of its kind utilising a hard-wearing polymer moulding construction. Opting for an isolator with this unique build provides benefits other standard isolators are not able to replicate.



Consistency: Bioquell Qubes are manufactured from the same mould, making the final product consistent and identical. Fabricated isolators are handmade parts that are bent and welded. This can result in inconsistent fit and potential leak risks.



User comfort: Moulding technology enables a repeatable and tested ergonomic shape to improve comfort by the user. Often cost and manufacturing practicality of stainless steel isolators results in a more “box-like” shape that can lack user-orientation in design.



Production time: A moulded design can allow for a delivery and validation in approximately 12 to 16 weeks from the time of order. Stainless steel isolators may require more significant lead times based on the production process.



Chamber integrity: The Bioquell Qube chambers are a single-piece moulded shell with less single parts to guarantee leak tightness. For stainless steel construction, each weld, joint and gasket can lead to a potential risk of leaks.



Validation: After installation, a Bioquell Qube, regardless of configuration, can be validated in 1 to 2 weeks due to consistency in its construction. Stainless steel isolators require lengthier time frames due to variability.



Ergonomics: Due to the moulding technology, the Bioquell Qube is consistently crafted with the user experience in mind, rather than a rigid box. A Bioquell Qube chamber is relatively light (617 lbs/ 280 Kg), optimal for minimal floor loads. Stainless steel is extremely heavy with a density of 8 times that of the Bioquell Qube polymer, thus significantly heavier for floor loads. A single person can even easily move the Bioquell Qube system for cleaning purposes.



Chemical resistance: The polymer is extremely stable, inert, and highly resistant to chemicals - including hydrogen peroxide vapour.

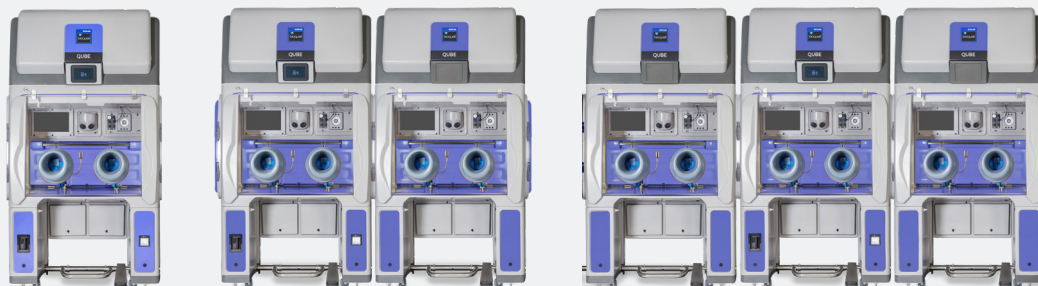
Find the right configuration for you

We work with you to build the Bioquell Qube isolator to meet your needs by offering a 2, 4 or 6 glove option that can be amended with a material pass through or RTP on either or both sides of the system selected.

Never slowdown your workflow as 4 and 6 glove options allow you to work in one or two chambers, while bio-decontaminating incoming supplies in the other.

Determine how many chambers

1-3 chambers



Select transfer chamber needs

0-2 transfer chambers or Rapid Transfer Ports



RTP available in 190mm or 270mm



Choose interior workspace

Select open or closed connections between workspaces that do not contain a hydrogen peroxide vapour generator

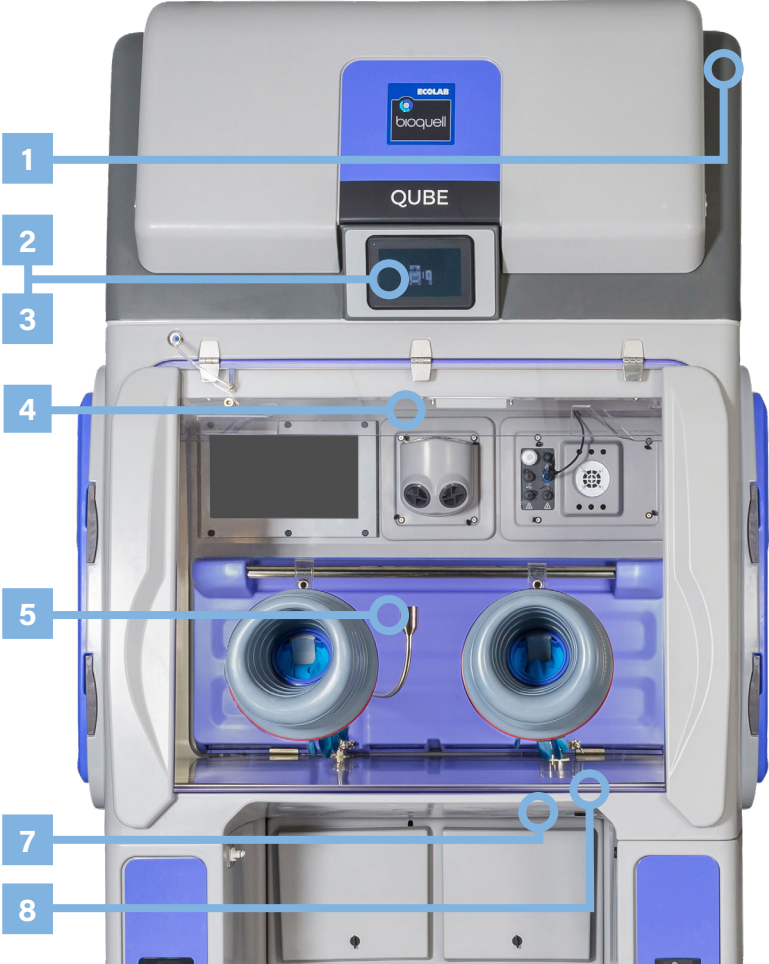


Numerous configurations and options to meet your needs

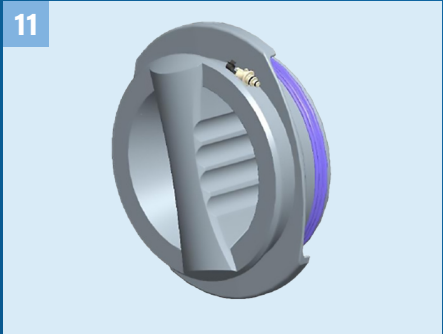
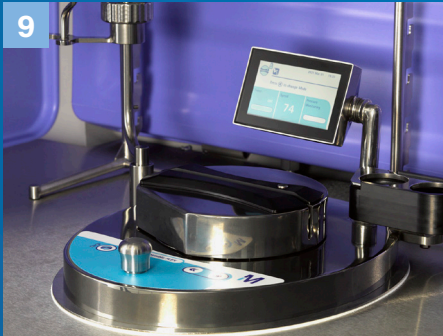


Accessories & features

While integrated bio-decontamination comes standard, optional features provide efficiencies and assurances to any process.



	Accessories	Feature
1	Ducted system	Typically used for negative pressure needs to help protect operators
2	Display monitor	Allows for useful information, such as SOPs, to be relayed within the chamber to the user
3	Audit trail	This provides a log of all activity within the system
4	Camera	For quality assurance or other purposes, users can monitor and record the work processed in the isolator
5	Central iso-kinetic cone	This is used for particle counting
6	Rapid Transfer Port (RTP)	Quick connect with vessel for adding or removing items from chamber
7	Drain connection	Used for bench top sterility test pumps
8	Tri-clover port for cable / tubing entry	This entry point allows additional cables or tubing to enter the chamber
9	Sterility test pump	This integrated option provides more space and greater ease of use
10	Active Air Head or AAH (viable) & Particle Counter (non viable)	Environmental monitoring to ensure Grade A aseptic processing
11	Glove tester	Delivers pressure decay testing of gloves and sleeves to help ensure a controlled environment



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Technical Specifications

Physical and safety data	Operating data	Power data
Dimensions and weight: Overall external: 1360 x 2335 x 843mm (53.5 x 91.9 x 33.2in) Inside chamber¹: 1100 x 750 x 540mm (43.3 x 29.5 x 21.3in) 280kg (617.3lbs)	Hydrogen peroxide liquid: 35% w/w Bioquell supply (Fits UN approved 150ml bottle with RFID) Air quality: ISO 14644-1 Class 5 (EU GMP Annex 1 Grade A) Airflow (downflow air velocity): Unidirectional 0.38m/s (+/-0.02) airflow at working height	Requirements (max): 230V AC, single phase, 50/60Hz 7.8A 120V AC, single phase, 50/60Hz 15.0A 100V AC, single phase 50/60Hz 15.0A Consumption (max)²: 1.8kW Process mode: QHPV: 0.53kW QEXT: 0.35kW QMTD: 0.05kW (Power comes via the QHPV) Supply: Installation category II

REFERENCE

- 1 Internal chamber shape is irregular and may affect the overall working volume. Please contact Ecolab for more information.
- 2 Additional power will be required for additional modules. The current and power quoted is for 2 QMTD's fitted to a QHPV unit, steritest pump, particle counter fitted and working and all internal sockets fully loaded in module. Maximum power is only drawn during the 'vapour distribution' stage and not through the whole bio-decontamination cycle.

For more information contact your **Ecolab Account Manager**

USE BIOQUELL PRODUCTS SAFELY. ALWAYS READ THE LABEL AND PRODUCT INFORMATION BEFORE USE.

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