

Bioquell QUBE – Steritest workstation

Sterility testing with integrated HPV decontamination



- **Intelligent modular design for user flexibility**
- **Rapid 20 minute bio-decontamination cycle***
- **High level 6-log sporicidal bio-decontamination technology**

Revolutionary new range of fully integrated HPV solutions for sterility testing

Sterility testing is required during the sterilisation validation process, as well as for routine quality control and detecting major contamination in a batch. The test environment should be as stringently controlled as an aseptic processing environment. Sterility testing is an extremely difficult process that must be designed to eliminate false positive results. False positive results are generally due to laboratory contamination from the testing environment or technician error.

To meet the challenges of sterility testing, Bioquell has developed a revolutionary new fully integrated hydrogen peroxide vapour (HPV) solution. The Bioquell QUBE offers a rapid sporicidal bio-decontamination process with a high level validated 6-log reduction in bioburden.

This in-built bio-decontamination system has been designed to complement a fully fitted and validated sterility test unit such as the market leading Millipore Steritest system.

Designed to act as a modular, barrier separation technology ('closed system'), the Bioquell QUBE provides a physical separation of operators to the sterility test process. The intelligent modular design principles give users flexibility in selecting the most suitable configuration for their individual process. This allows users to build the Bioquell QUBE system to their process requirements (e.g. a single module if space is at a premium, up to a full 3 workstation unit for high volume throughput).

The closed barrier technology also enables the user to apply automated HPV biological decontamination. Within a single module, a rapid 20 minute bio-decontamination cycle* allows fast and efficient material transfers. The in-built flexible gassing options also allow the user to bio-decontaminate multiple interfaced Bioquell QUBE modules or separately bio-decontaminate test material and samples as part of a rapid gassing transfer process. To help ensure users can maximise working area whilst maintaining aseptic conditions, samples and waste removal can be made via a transfer hatch or rapid gassing port.

* When using a single unit and depends on loading and absorbency of chamber contents.



Image 1. Simple, easy to use touch screens enable a high level of automation

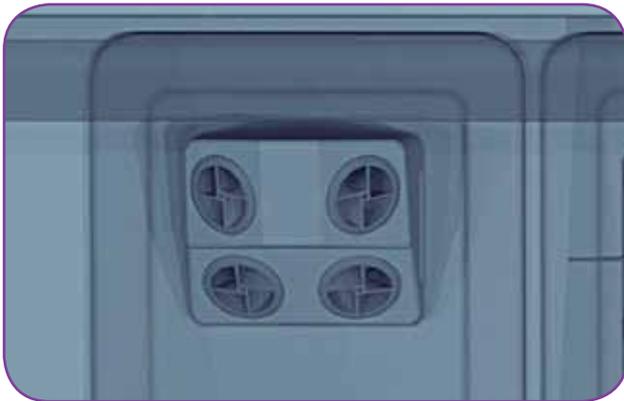


Image 2. Specially designed vents to provide complete 3-D surface coverage during HPV bio-decontamination



Image 3. Bioquell hydrogen peroxide (150ml) with RFID technology for traceability

Unique moulding technology and pre-determined gas cycle development ensure a system that can be on-site and operating rapidly. One level stainless steel work platforms ensure load and material transfer ergonomics are fully optimised for seated working.

Integrated environmental monitoring systems for total particulate and viable monitoring offer three levels of implementation, up to continuous particle monitoring used for risk management with real-time deviation alarm.

High level automation offers simple to use leak testing via a high resolution soft touch screen together with HPV and batch print record reporting.

6-log sporicidal HPV technology ensures bio-decontamination of outer surfaces of all samples and test materials, reducing incidence of false positives.

EU GMP Grade A / ISO 5 compliant environment ensured by both uni-directional airflow and Bioquell's unique isolator technology which minimises joints and potential leak points.

Bioquell batch tested and approved hydrogen peroxide ensures optimal bio-decontamination cycles whilst RFID technology gives batch and expiry information for both traceability and audit purposes.

A two year warranty as standard is also supplied which coupled with intelligent system design, minimises both maintenance costs and downtime due to any excess servicing.

Your local distributor:

Disclaimer: Bioquell UK Ltd or its affiliates, distributors, agents or licensees (together 'Bioquell') recommends that customers ensure that the requisite level of bio-decontamination is achieved using standard biological indicators such as 6-log *Geobacillus stearothermophilus* spores; and the Bioquell technologies, subject to appropriate cycle development, are designed to be able to provide such levels of bio-deactivation.

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