

Bioquell | HPV-CI



Image 1. Bioquell HPV-CIs provide a simple, easy to use indication of a successful Bioquell HPV bio-decontamination process

Bioquell HPV-CI is a simple visual indicator of the effectiveness of a Bioquell hydrogen peroxide vapor (HPV) bio-decontamination cycle. It has been developed to complement standard biological indicators*.

Each pack of Bioquell HPV-CI contains indicator cards with a series of symbols that change color when exposed to Bioquell HPV. These symbols use a color-changing chemical dye specifically designed for Bioquell's HPV bio-decontamination process. When the required bio-decontamination conditions have been met, the indicator symbols change from blue towards white.

During the HPV bio-decontamination cycle, or immediately after completion of the cycle, the color of the indicator symbol can be compared with pre-printed reference colors (shown as halos) on the card. These reference colors provide a visual indication of the progressive (2-log, 4-log, 6-log and >6-log) reduction in bioburden in relation to a biological indicator with a D-value of 1.75 minutes. The change in color helps to provide an instant indication of the efficacy of a Bioquell HPV cycle. This efficacy can be later confirmed following the seven day incubation period of standard biological indicators.

Additionally, HPV-CIs can be used to determine the distribution of Bioquell's HPV within a room or enclosure. This allows a rapid assessment of potential problematic areas and the impact of any products/equipment/furniture within the target environment. From this assessment, the deployment of Bioquell HPV equipment or specific cycle parameters can be reviewed and further bio-decontamination cycles conducted if necessary, helping to minimize the time taken to reach an assured cycle. Again, the efficacy and coverage can be later confirmed following the seven day incubation period of standard biological indicators.

- **Chemical indicator designed for Bioquell's HPV bio-decontamination process**
- **Simple, visible indication of a successful HPV bio-decontamination cycle**
- **Rapid and easy to read: real-time result**

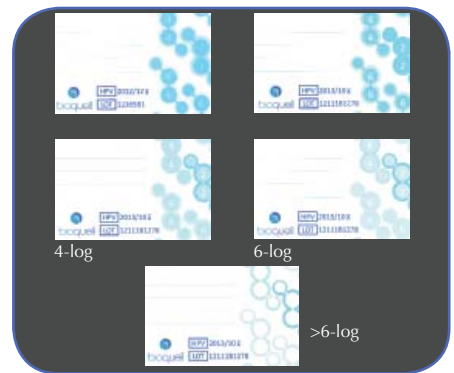


Image 2. Indicator symbols on the Bioquell HPV-CI card change from a blue color towards white (matched to a reference halo) following a Bioquell HPV bio-decontamination



Image 3. After a Bioquell HPV bio-decontamination, the color of the indicator portion can be used to provide an early indication of the reduction in bioburden (e.g. >6-log)

Technical specification

Specification	Visual indicator cards with a chemical indicator to signify a 2-log, 4-log, 6-log or >6-log reduction in bioburden with a pre-determined D-value of 1.75 minutes following a bio-decontamination cycle using Bioquell HPV technology*
	Color change from blue towards white
	Suitable for all Bioquell HPV generators
Wallet sizes	20 CI cards per foil wallet
Box sizes	Boxes carry 5 foil wallets**

Key features

Each Bioquell HPV-CI card offers a large indicator area allowing easy readout and interpretation. This indicator area changes from blue towards white during a Bioquell HPV bio-decontamination cycle. The colour change from blue towards white is obvious and easily identifiable. The colour of the indicator portion has been designed to match the reference halos (2-log, 4-log or 6-log) at the corresponding point of the log reduction in *Geobacillus stearothermophilus* biological indicators. At >6-log, the indicator portion becomes white*.

On the indicator card, space is also provided for writing bio-decontamination process details e.g. location used, item processed.

Each batch of Bioquell HPV-CI is thoroughly tested to ensure consistent characteristics are achieved. Lot numbers are provided on each chemical indicator for product traceability and audit purposes.

Operation

The Bioquell HPV-CI cards must be kept in the sealed wallet until required. Once opened, they should be kept in the foil wallet inside the box and used within 14 days. Ongoing exposure to the air can cause the colors to continue to fade over time.

Prior to the bio-decontamination cycle, the indicator cards should be placed in suitable locations within the target zone. Ideally, the cards should be visible from outside the target zone. After the Bioquell HPV process, each card provides an instant indication that a 2-log, 4-log, 6-log and >6-log reduction in bioburden has been achieved.

*Bioquell HPV-CIs are not designed to replace standard biological indicator testing. Specifically no regulatory claims or regulatory equivalence to biological indicators are made by Bioquell in respect of the Bioquell HPV-CIs.

**Indicated on batch/expiry label

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Applications

Bioquell HPV-CI can be used in many different market sectors including food processing, pharmaceutical production, life sciences, defense, and healthcare. They are suitable for various applications including cycle development, efficacy testing of new equipment and as part of a program for faster validation and re-validation of aseptic workstations and cleanrooms. They can also be used to distinguish between processed and unprocessed items.

Bioquell HPV-CI is only to be used with Bioquell HPV technology.

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