

BIOQUELL BIOLOGICAL INDICATOR

CONSISTENT AND RELIABLE 6 LOG BIOLOGICAL INDICATOR FOR HYDROGEN PEROXIDE VAPOR DECONTAMINATION



The Bioquell Biological Indicator (BI) is specifically designed for the Bioquell hydrogen peroxide vapor process. Each BI is inoculated with 6-log *Geobacillus stearothermophilus* ATCC 12980 endospores to provide assurance that a 6-log reduction is achieved on every bio-decontamination cycle. These spores are selected due to their resistance to many different bio-decontamination processes, including hydrogen peroxide vapor. Every Bioquell BI is manufactured by Bioquell to ensure the highest level of consistency and reliability.

KEY FEATURES

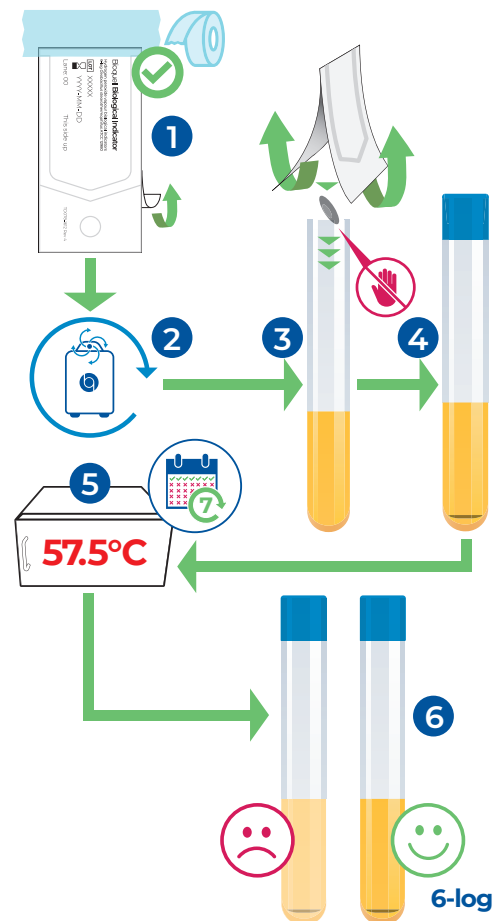
- *Geobacillus stearothermophilus* specifically recommended for hydrogen peroxide vapor bio-decontamination
- A minimum of 1.0×10^6 spores are inoculated on each carrier disc
- Specially-designed disc and rigorous manufacturing process ensures low risk of false positives
- Enclosed in high porosity Tyvek pouch enabling rapid hydrogen peroxide vapor penetration through to the disc
- Easy to handle pouches ideal for quick hanging of the BIs inside isolators or other enclosures
- Consistent, trustworthy results ensuring a 6-log sporicidal reduction is accurately achieved



HOW TO USE BIOQUELL BI

- 1 Place the Bioquell BIs in locations to be challenged throughout the target enclosure or in previously validated areas.
 - The printed side of the indicator pouch is the inoculated side. This side should always be placed face up although the pouch should be positioned such that all surfaces are exposed to hydrogen peroxide vapor to prevent false positive results.
- 2 Start the Bioquell cycle and once the cycle is complete, the indicators should be retrieved from the enclosure locations.
- 3 Place the BI in the culture promptly without touching the disc
- 4 Seal the cap on the vial
- 5 Bioquell recommends culturing TSB at 57.5°C
- 6 If your broth remains clear you have achieved a 6-log kill

Please remember, Bioquell BI's should be kept in the sealed foil wallet until required. All Bioquell BI boxes come with a multilingual instruction leaflet.



BUILDING THE BIOQUELL BI

Prior to inoculation on the carrier disc, the endospores undergo a set of intricate cleaning steps to remove surplus media and cellular debris that can lead to BI variability. To further enhance the consistency of Bioquell BIs, the shape and surface finish of the carrier disc facilitates the even distribution of the spores across the disc. Every step taken reduces the risk of inaccurately recording a decontamination cycle as a failure when it was actually due to a false positive.

Each Bioquell BI batch is thoroughly tested to ensure a consistent biological challenge for hydrogen peroxide vapor bio-decontamination processes. Bioquell BIs are shipped with a certificate of analysis that specifies the average number of microorganisms on each carrier disc and the D-value.* Batch lot numbers are also marked on each biological indicator for product traceability.

* Calculated decimal reduction time in minutes required for a 1-log - 90% - reduction of the microorganisms under specified lethal conditions.

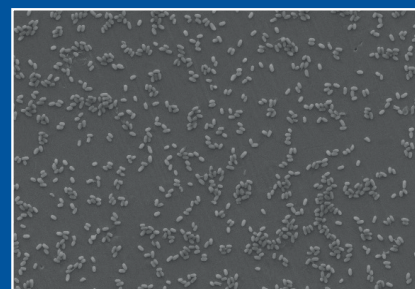
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Specification:

- Biological Indicators provide assurance of a 6 log sporicidal reduction following a hydrogen peroxide vapor bio-decontamination cycle.
- Type: 6 log₁₀ *Geobacillus stearothermophilus* ATCC 12980
- Suitable for all Bioquell hydrogen peroxide vapor equipment.

Packaging Contents	
Unit Description	Exterior package is a box Hosted inside are resealable foil wallets, and Instruction leaflet Each box carries 1 or 5 foil wallets*
Foil Wallet Description	Each resealable foil wallet contains 20 BI pouches
Storage	Shelf life of 12 months Storage temperature limits of 2°C to 25°C
Dimensions (WxHxD)	Box 111 x 165 x 60mm (4.37 x 6.50 x 2.36 in) Foil wallet: 100 x 158 x 15mm (3.94 x 6.22 x 0.59 in)
Tyvek Pouch	Dimensions: 60 x 30 x 1.0mm (2.36 x 1.18 x 0.94 in) Pre-punched hole: 6mm (0.24in) in diameter Materials: 1073B
BI Disc	Dimensions: Discs are 9mm in diameter Material: Carrier disc is formed out of 316L grade stainless steel
Unit Weight	20 units, packaged is 0.346kg (0.76lb) 100 units, packaged is 0.397kg (0.88lb)

*Indicated on batch/expiry label



Scanning electron microscope image showing even *Geobacillus stearothermophilus* endospore dispersal across Bioquell BI carrier disc.

The Americas

Bioquell Inc
E: solutions@bioquell.com
W: www.bioquell.com
T: +1 215 682 0225

Global

UK Headquarters
Bioquell UK Ltd
T: +44 (0)1264 835 835

France
Bioquell SAS
T: +33 (0)1 43 78 15 94

Germany
Bioquell GmbH
T: +49 2173 599 4040

Ireland
Bioquell Ireland
T: +353 (0)61 603 622

China
Bioquell Shenzhen Technology Company Ltd
T: +86 755 8635 2622

Singapore
Bioquell Asia Pacific Pte Ltd
T: +65 6505 6758



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