

Consistent and Reliable 6-log Biological Indicator for Hydrogen Peroxide Vapor Decontamination



Bioquell™ Biological Indicator

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.



EFFECTIVE

- ▲ *Geobacillus stearothermophilus* specifically recommended for hydrogen peroxide vapor bio-decontamination
- ▲ A minimum of 1.0×10^6 spores are inoculated on each carrier disc



RELIABLE

- ▲ 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

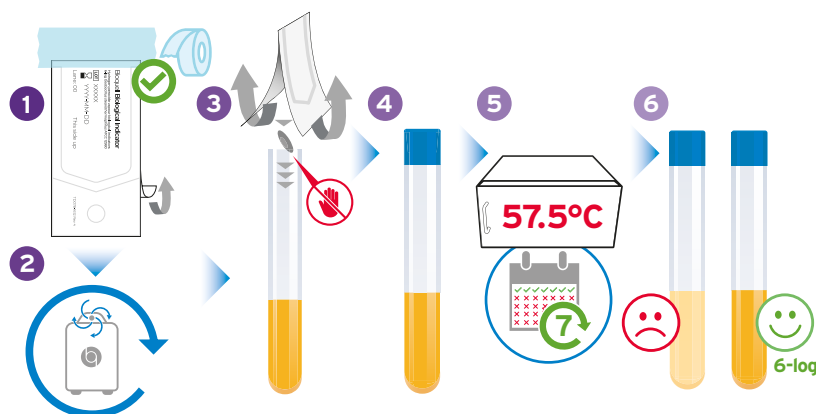


CONVENIENT

- ▲ 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

Bioquell™ Biological Indicator

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 Tryptone Soya Broth (TSB) promptly without touching the disc.
- 4 Seal the cap** on the vial.
- 5 Bioquell recommends** incubating 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 all have 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.

TECHNICAL SPECIFICATIONS

SPECIFICATION

- ▲ Biological Indicators provide assurance of a 6-log sporidical 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 from date of manufacture. 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 (0.24 in) in diameter

Materials: 1073B

BI Disc:

Dimensions: Discs are 9mm in diameter

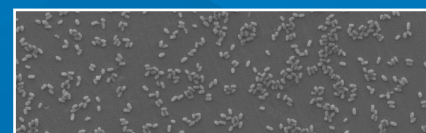
Material: Carrier disc is formed out of 316 L grade stainless steel

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.

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

For regional office details, please visit bioquell.com

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