

**AN2202** Biological Indicator Strips  
**AN2203** Self-Contained Biological Indicators  
**AN2205.10** Self-Contained Biological Indicator Incubator

**Anprolene**<sup>®</sup>  
gas sterilisation

**EOGas**<sup>®</sup>

**Biological Indicators**  
Quality Assurance Products  
designed for use with  
Anprolene and EOGas sterilisers.

Verification of a successful sterilisation process can be ascertained through the use of biological indicators, which are a reliable and inexpensive way to determine sterility assurance. These ensure that the sterilisation cycle had been effective in killing 10<sup>6</sup> spores of the touch bench mark bacterium, *Bacillus atrophaeus*, by incubating them for at least 48 hours at the end of the cycle. The biological indicators are placed in the most challenging area of the load to be sterilised. If there is no bacterial growth after appropriate incubation, the sterilisation process can be deemed successful.

## AN2202 Biological Indicator Strips

After EtO exposure, the strips need to be removed from their sleeves aseptically and cultured in soybean casein digest broth at 30-35°C for 7 days.

**Quantity:** 100/box

**Expiration:** 24 months after manufacture.



## Instructions

### Sterilisation:

1. Place spore strips inside representative materials to be sterilised and/or package as usual.
2. Place the spore strip package in the most challenging area of the load.
3. Process the load as usual.
4. After sterilisation remove the spore strips and forward to a test laboratory.

### Test Laboratory:

1. All testing should be performed in a clean, dust-free room and within confines of a laminar flow hood. All transfers and manipulations must be conducted with rigid aseptic techniques to avoid "false positives".
2. Procedure:
  - a. Aseptically withdraw spore strips with sterile forceps and transfer to individual tubes containing 10-15mL sterile soybean casein digest broth.
  - b. Incubate spore strips at 30-35°C for 7 days.
  - c. Observe tubes daily for growth: Cloudy= growth= non-sterile  
Clear= no growth= sterile.

Test strip cultures should show no growth if adequate sterilisation has been achieved.

# Biological Indicators

## AN2203 Self-Contained Biological Indicators

These self-contained biological indicators (BIs) set the gold standard for sterility assurance. They contain a minimum of  $1 \times 10^6$  *Bacillus atrophaeus* spores. No need for aseptic conditions as they are self-contained, with the growth media stored inside the BI in a glass vial. Results are available in just 48 hours.

**Quantity:** 25/box

**Expiration:** 24 months after manufacture.

### Instructions

#### Exposure:

1. Place BIs inside representative materials to be sterilised and/or package as usual.
2. Place the BIs in the most challenging area of the load.
3. Process the load as usual.
4. After sterilisation remove the BIs. The chemical indicator on the label changes from blue to brown when exposed to EtO, distinguishing between exposed and unexposed units.

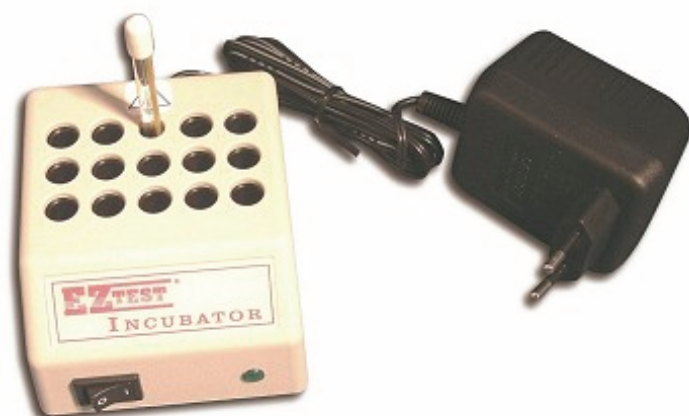
NOTE: A brown colour does not indicate acceptable sterilisation.

#### Incubation:

To activate, gently squeeze the unit to crush the glass vial inside releasing the growth media. Media should be orange and clear before incubation. Place the activated BI in an upright position in an incubator (35-39°C).

#### Interpretation:

1. Examine the BIs at regular intervals for any colour change (i.e. 18, 24, 48 hours). The appearance of a cloudy yellow media indicates bacterial growth. No colour change indicates adequate sterilisation.



## AN2205.10 Biological Control Incubator

This 14-well incubator is designed for use with the AN2203 self-contained biological indicators, which are incubated at 35-39°C for at least 48 hours.

**Power supply:** 120V/ 60Hz or 220V/ 50Hz

**Well diameter:** 0.7cm

**Well depth:** 2.5cm

### Free Key Operator Training

*Andersen provides free training for as many operators as required, for the lifetime of the cabinet.*

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