3M ESPE Attest™ 1261/1261P Biological Indicator

(English)

Product Description:
The Attest™ 1261/1261P Biological Indicator (blue cap), manufactured for 3M ESPE, is designed for monitoring 270°F (132°C) gravity displacement steam sterilization processes. The presence of active *Geobacillus stearothermophilus* spores is detected by a visual color change (media turns yellow). The yellow color change indicates a sterilization process failure. The final readout of a negative result (media remains purple) is made after 24 hours of incubation. A sterilizer must have a 1.5 minute come-up time to kill the Attest 1261/1261P biological indicator in 3 minutes. If the come-up time is < 1.5 minutes, extend the cycle time to 4 minutes to achieve consistent inactivation.

Indications:
Use the Attest 1261/1261P Biological Indicator to monitor:
1. 270°F (132°C) gravity displacement steam sterilization cycles.

Monitoring Frequency:
Attest biological indicators should be placed in an appropriate test tray or package, and be used to monitor every load. This presents an appropriate challenge and improves the performance of the sterilization process.

Precautions: Do not use the Attest 1261/1261P Biological Indicators to monitor:
1. 270°F (132°C) or 250°F (121°C) vacuum assisted steam sterilization cycles.
2. 250°F (121°C) gravity displacement steam sterilization cycles.
3. Dry heat, chemical vapor, ethylene oxide or other low temperature sterilization processes.

Contraindications: None

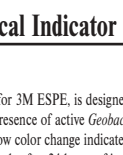
WARNING:

There is a glass ampule inside the plastic vial of the biological indicator.

- **Crushing or excessive handling of the biological indicator before cooling may cause the glass ampule to burst that may result in personal injury from flying debris.**
- **Wear safety glasses and gloves when removing biological indicators from the sterilizer.**
- **Wear safety glasses when crushing biological indicator.**
- **Handle the biological indicator by the cap when crushing and tapping.**
- **Do not use your fingers to crush the glass ampule.**
- **Do not roll the biological indicator between your fingers to wet the spore strip.**

Directions for Use:
1. Identify the Attest biological indicator by writing the sterilizer, load number, and processing date on the indicator label.
2. Place the Attest 1261/1261P biological indicator in an appropriate test package or tray according to recommended practices.
   ***Unwrapped metal instruments or hard goods with no porous items run at 270°F (132°C) for ≥3 minutes in a gravity displacement cycle*:**
   • Place the Attest 1261/1261P biological indicator in an unwrapped instrument tray with a representative number and type of instruments normally processed. AAMI suggests placing a biological indicator in an empty tray.
   ***Unwrapped metal instruments or hard goods with porous items run at 270°F (132°C) for ≥10 minutes in a gravity displacement cycle*:**
   • Place the Attest 1261/1261P biological indicator in an unwrapped instrument tray with a representative number and type of instruments normally processed. AAMI suggests placing a biological indicator in an empty tray but include porous items if applicable.
   ***Wrapped metal instruments or hard goods run at 270°F (132°C) for ≥10 minutes in a gravity displacement cycle*:**
   • Place the Attest 1261/1261P biological indicator in a wrapped instrument tray with a representative number and type of instruments normally processed. AAMI suggests placing a biological indicator in an empty tray but include porous items if applicable.
   Washer sterilizer cycles run at 270°F (132°C) for ≥3 minutes in a gravity displacement cycle:
   • Place the Attest 1261/1261P biological indicator in a representative hard goods item (e.g., instrument tray or basin) from the sterilizer load after the wash cycle to monitor the sterilization cycles. Do not subject the Attest biological indicator to the wash cycle. Contact the washer sterilizer manufacturer for recommendations for monitoring washer sterilizer cycles that cannot be interrupted before the sterilization cycle or cycles that run at temperatures other than 270°F (132°C) and times < 3 minutes.
   ***Container systems run at 270°F (132°C) in a gravity displacement cycle*:**
   • Place the Attest 1261/1261P biological indicator in the areas determined by product testing to provide the greatest challenge to the sterilization process.
   ***Patient Care trays run at 270°F (132°C) for ≥ 3 minutes a gravity displacement cycle*:**
   • Place the Attest 1261/1261P biological indicator in a tray or container of medical devices that is going directly to patient use to ensure that the medical devices are properly sterilized. Follow aseptic techniques when retrieving the Attest biological indicator from the tray or container for incubation.
3. Place the test tray or package in a full load in the most challenging area for the sterilant. This is generally on the bottom shelf, near the door and over the drain.
4. Process the load as usual.
5. After the completion of the cycle and while wearing safety glasses and gloves, fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest biological indicator. Note WARNINGS above. Handle the biological indicator by the cap when crushing. Do not use your fingers to crush the glass vial.
6. When the biological indicator is not contained in a test package or any other heat absorbing packaging material, remove the biological indicator from the sterilizer and allow to cool for an additional 10 minutes prior to crushing.
7. When the biological indicator is contained in a test pack or other heat absorbing packaging material, the test pack or any other heat absorbing packaging material should be removed from the sterilizer and opened for 5 minutes to dissipate heat prior to removing the biological indicator. Allow the biological indicator to cool outside the test pack for an additional 10 minutes prior to crushing.
8. Check the chemical indicator on the label of the biological indicator. A color change from rose to brown confirms that the biological indicator has been exposed to the steam sterilization process. This color change does not indicate that the process was sufficient to achieve sterility. If the chemical indicator is unchanged, check the sterilization process controls and investigate placement of the biological indicator in the sterilizer.
9. While wearing safety glasses, crush and incubate the biological indicator at 56 ± 2°C (133 ± 3°F).

Attest Incubator	**Attest Incubator**
120 volt (North American Usage)	**240 volt (International Usage)**
Model 116 (14 indicators)	Model 118 (14 indicators)
Model 126 (28 indicators)	Model 128 (28 indicators)
Top tier of Model 130	Top tier of Model 131
(14 indicators)	(14 indicators)



   A. While wearing safety glasses, position indicator in metal block (see Figure 1). Place bottom of the indicator into the incubator's metal heating block so that the indicator is at an angle of approximately 45°.
   B. Push the indicator straight back. (See Figure 2). This crushes the media ampule and activates the indicator. Be sure that the cap will remain above the metal block when the indicator is pushed back.
   C. Push the activated indicator down to seat it in the metal heating block. (See Figure 3). Be sure that the cap remains above the metal block when seated in the incubator.
10. Incubate at least one unprocessed Attest biological indicator (positive control) each day a processed indicator is incubated. The positive control indicator should be from the same manufacturing date and lot number as the processed indicator in the incubator.
11. Write a "C" and a date on the label of the positive control indicator. Crush and incubate the control at 56 ± 2°C (133 ± 3°F).
    The purpose of the positive control is to ensure:
    *correct incubation conditions
    *viability of indicators (incorrect storage conditions could affect those indicators that are within their stated shelf life)
    *capability of media to promote rapid growth
12. Incubate processed and control biological indicators for 24 hours at 56 ± 2°C (133 ± 3°F).
    Incubation Times:

Early Detection	12 hours
	18 hours
Final Readout	24 hours

13. The appearance of a yellow color in the processed indicator demonstrates bacterial growth and a possible sterilization process failure. No color change (media remains purple) indicates that sterilization conditions have been met. A final readout of a negative result is made after 24 hours of incubation. The positive control indicator should show a yellow color change for the processed indicator results to be valid.
14. Record the processed and control biological indicator results. Act on any positive test as soon as the first evidence of growth is noted according to your facility policy. Always retest the sterilizer and do not use the sterilizer until the biological indicator results are negative.

Disposal: Dispose of used Attest biological indicators according to your health care facility policy. You may wish to autoclave any positive biological indicators at 121°C (250° F) for at least 15 minutes, or at 132°C (270°F) for 10 minutes in a gravity displacement steam sterilizer, or at 132°C (270°F) for 4 minutes in a vacuum assisted steam sterilizer.

Storage and Shelf Life:
- Store Attest biological indicators under normal room conditions: 59-86°F (15-30°C), 35-60% relative humidity.
- Do not store these biological indicators near sterilants or other chemicals.
- Attest™ 1261 Biological Indicators have a 2-year shelf life from the date of manufacture.
- The lot and expiration on each package is described as:
  - Year of expiration
  - Month of expiration
  - Lot ID

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty
3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability
Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

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