3M™ Attest™ 1264/1264P Biological Indicator

Product Description
The 3M™ Attest™ 1264 Biological Indicator (green cap) is designed for monitoring of ethylene oxide (E0) sterilization processes. The presence of *Bacillus atrophaeus* 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 green) is made after 48 hours of incubation.

Indications for Use
Use the Attest™ 1264 Biological Indicator to monitor:

1. All ethylene oxide sterilization cycles.

Contraindications
None.

Warnings
- Butyl, neoprene, or nitrile gloves should be worn when removing the biological indicator from the load prior to the completion of aeration.
- 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.
  - Wear safety glasses when crushing the biological indicator.
  - Handle the biological indicator by the cap when crushing.
  - Do not use your fingers to crush the glass ampule.

Precautions
Do not use the Attest™ 1264 biological indicator to monitor sterilization cycles which it is not designed to challenge:

1. Steam sterilization cycles.
2. Dry heat, chemical vapor, or other low temperature sterilization processes.

Monitoring Frequency
Follow facility Policies and Procedures which should specify a biological indicator monitoring frequency compliant with professional association recommended practices and/or national guidelines and standards. As a best practice and to provide optimal patient safety, 3M recommends that every sterilization load be monitored with a biological indicator in an appropriate Process Challenge Device (BI PCD).

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™ 1264 biological indicator in a Process Challenge Device (BI PCD) as recommended by professional association guidelines or national standards for hospital practice (e.g., AAMI routine BI syringe test pack).
3. Place the BI PCD in a full load in the most challenging area for the sterilant. This is generally in the center of the load.
4. Process the load as usual.
5. After sterilization two options exist:
   a. Aeration of BI PCD Prior to Incubation

      Aerate the other packs from the load for the same amount of time as the BI PCD. At the end of the aeration cycle, remove the biological and chemical indicators from the BI PCD. Dispose of the remaining BI PCD components according to the healthcare facility's policy.

   b. Removal of Biological Indicator from BI PCD Prior to Aeration

      Open the sterilizer door according to the manufacturer's instructions; transfer the load to the aerator and retrieve the BI PCD. (If a sterilizer with aeration capability is used, follow the manufacturer's instructions for opening the door and remove the BI PCD prior to the aeration cycle.) Remove the biological and chemical indicator from the BI PCD. Return the remainder of the BI PCD to the load for aeration according to the healthcare facility's policy. When it is necessary to handle items that are not fully aerated, butyl, neoprene, or nitrile gloves should be worn. The breathing zone of personnel should be monitored to verify the safety of the practices followed.
6. Check the chemical indicator on the label of the biological indicator. A color change to green confirms that the biological indicator has been exposed to an EO 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.
7. Incubate the biological indicator at 37 ± 2°C (99 ± 3°F).

Attest™ Incubator 120 volt (North American Usage)	**Attest™ Incubator 240 volt (International Usage)**
Model 127 (28 indicators)	Model 129 (28 indicators)

a. 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.

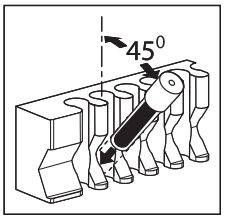

Figure 1

8. 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 lot code as the processed indicator in the incubator.
9. Write a "C" and a date on the label of the positive control indicator. Crush and incubate the control at 37 ± 2°C (99 ± 3°F).

   The purpose of the positive control is to ensure:

   - correct incubation conditions
   - viability of indicators (incorrect storage conditions could adversely affect even those indicators which are within their stated shelf life)
   - capability of media to promote rapid growth.

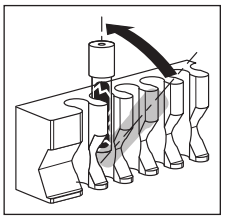

Figure 2

10. Incubate processed and control biological indicators for 48 hours at 37 ± 2°C (99 ± 3°F).

    Incubation Times:

    Early Detection 12 hours
    18 hours
    24 hours

    Final Detection 48 hours

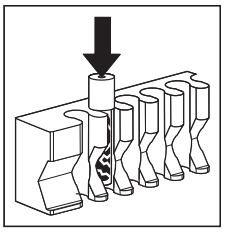

Figure 3

11. The appearance of a yellow color in the processed indicator demonstrates bacterial growth and a sterilization process failure. No color change indicates an adequate sterilization process. A final negative result is made after 48 hours of incubation. The positive control indicator should show a yellow color change for the processed indicator results to be valid.
12. Record the processed and control biological indicator results. Act on any positive test as soon as the first evidence of growth is noted. Always retest the sterilizer and do not use the sterilizer until the biological indicator test results are negative.

Storage

- Best stored in the original box under normal room conditions: 15-30°C (59-86°F), 35-60% relative humidity.
- Do not store these biological indicators near sterilants or other chemicals.

Disposal

Dispose of used Attest™ biological indicators according to your healthcare facility's 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.

Explanation of Symbols:

Caution, see instructions for use

Do not reuse

Use by date

LOT Batch code

Manufacturer

Date of manufacture

REF Catalogue Number

Made in U.S.A. by
3M Health Care
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3M.com/infectionprevention

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