

3M™ Attest™ 1262/1262P Biological Indicator

Product Description

The 3M™ Attest™ 1262 Biological Indicator (brown cap) is designed for monitoring steam sterilization processes. The presence of *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 48 hours of incubation.

Contraindications

None.

Warnings

There is a glass ampoule 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 and gloves when removing the biological indicator from the sterilizer.
- 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™ 1262 Biological Indicator to monitor sterilization cycles which it is not designed to challenge:

1. 132°C (270°F) gravity steam sterilization cycles, ≤3 minutes.
2. Dry heat, chemical vapor, ethylene oxide sterilizers, 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 (PCD) i.e., BI challenge test pack.

Directions for Use

1. Identify the Attest™ biological indicator by writing the sterilizer, load number, and processing date on the indicator label.
2. Place an Attest™ biological indicator horizontal or cap up in an appropriate test tray or package according to recommended practices. Appropriate test trays or packages for loads containing:

Fabric packs run at 121°C (250°F) for ≥30 minutes in a gravity sterilizer or at 132°C (270°F) for ≥4 minutes in a vacuum assisted cycle:

- Attest™ 1262 biological indicator in an AAMI 16 towel pack.

Wrapped metal instruments or hard goods run at 121°C (250°F) for ≥20 minutes in a gravity cycle:

- Attest™ 1262 biological indicator in a wrapped hard goods item (e.g., instrument set) from the load. Include porous items if applicable.

Wrapped metal instruments or hard goods run at 132°C (270°F) for ≥4 minutes in a vacuum assisted cycle:

- Attest™ 1262 biological indicator in an AAMI 16 towel pack or in a wrapped hard goods item (i.e., instrument tray) from a load with porous items if applicable.

Single wrapped metal instruments or hard goods run at 132°C (270°F) for ≥4 minutes in an express vacuum assisted cycle.

- Attest™ 1262 biological indicator in a single wrapped instrument tray or hard goods from the load. Do not process items with lumens or porous materials in this cycle.

Unwrapped metal instruments or hard goods with no porous items run at 121°C (250°F) for ≥15 minutes in a gravity cycle.

- Attest™ 1262 biological indicator in an unwrapped hard goods item (e.g., instrument set) from a load.

Unwrapped metal instruments or hard goods with no porous items run at 132°C (270°F) for ≥3 minutes in a vacuum assisted cycle.

- Attest™ 1262 biological indicator in an unwrapped hard goods item (e.g., instrument tray) from the load. AAMI suggests placing a biological indicator in an empty instrument tray.

Unwrapped metal instruments or hard goods with porous items run at 132°C (270°F) for ≥4 minutes in a vacuum assisted cycle.

- Attest™ 1262 biological indicator in an unwrapped hard goods item (e.g., instrument tray) from the load. Include porous items.

Container systems run at 121°C (250°F) in gravity cycles and 132°C (270°F) in a vacuum assisted cycles:

- Attest™ 1262 biological indicators in the areas determined by product testing to be the most resistant.

Table top gravity sterilizers that run from 121°C-132°C (250°F-270°F) with a come-up time of ≥2 minutes.

- Attest™ 1262 biological indicators in a test tray or package that is representative of the load and creates the greatest challenge. Include porous items if applicable.

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 thermal gloves, fully open the sterilizer door for a minimum of 5 minutes prior to removing the Attest™ biological indicator.

Note Warnings above

6. When the biological indicator is not contained in a test package or 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 up for 5 minutes to dissipate heat prior to removing the biological indicator. Then 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/black 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.

9. While wearing safety glasses, crush and incubate the biological indicator at 56 ± 2°C (133 ± 3°F).

Attest™ Incubator 120 volt

(North American Usage)

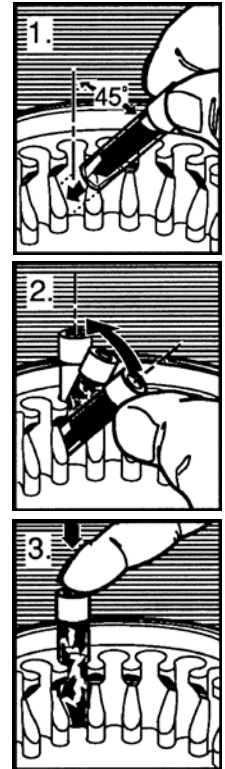
Model 116 (14 indicators)

Attest™ Incubator 240 volt

(International Usage)

Model 118 (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 lot code 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 adversely affect even those indicators which are within their stated shelf life)
 - capability of media to promote rapid growth
 12. Incubate processed and control biological indicators for 48 hours at 56 ± 2°C (133 ± 3°F).



Incubation Times:

- Early Detection 12 hours
- 18 hours
- 24 hours
- Final Detection 48 hours

13. 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.
14. Record the sterilized 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 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
- Batch code
- Manufacturer
- Date of manufacture
- Catalogue Number

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