3M

Attest™
Biological Monitoring System

Technical Product Profile

A Technical Service Publication

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Introduction

The Attest™ biological monitoring system is a convenient, reliable system for monitoring steam sterilization. This biological monitoring system has been a routine component of the quality assurance program of thousands of hospitals for two decades.

Biological indicators and an incubator make up the Attest™ system. The unique self-contained design of biological indicator makes it easy to use, easy to read, and provides reliable results. These indicators may be incubated within the dental office or may be sent to a microbiology lab for incubation and interpretation.

Product Description

Indicators

The Attest™ indicator system includes two separate biological indicators, each constructed to ensure optimal reliability in the quality assurance program of any healthcare facility. All Attest™ indicators are self-contained (i.e., contain both the dry spore strip and the growth medium). This design eliminates the possibility of contamination which may occur with spore strips in glassine envelopes when they are transferred to the growth medium. Also, the one spore per vial design provides information about the incubation and sterilization process that may not be obtainable with a two spore per vial design.[1]

Attest™ indicators are used routinely in steam sterilizers and are an important, practical part of any healthcare facility's quality assurance program.

The Attest™ monitoring system meets all the biological monitoring requirements suggested by the American Dental Association (ADA)[2], the Association for the Advancement of Medical Instrumentation (AAMI)[3,4], Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[5], Association of Operating Room Nurses (AORN)[6], American Society for Healthcare Central Service Personnel (ASHCSP)[7], the U.S. Military (Standard No. 969)[8] and the Centers for Disease Control (CDC)[9].

The entire Attest™ system is color coded for quick reference and easy use.

Color Coding	Sterilization Process Monitored	Attest™ Indicators	Attest™ Incubators 110/120 volt	Attest™ Incubators 220/240 volt
Brown	Steam (except 270°F/132°C gravity displacement)	1262P	Model 116 (14 vials) 133 ± 3°F (56 ± 2°C)	Model 118 (14 vials) 130 ± 3°F (56 ± 2°C)
Blue	Steam, gravity displacement 270°F/132°C	1261P	see above	see above

This product profile pertains to the Attest™ biological indicator system that requires 24-48 hours incubation.

Steam Indicators (Catalog numbers 1261P, 1262P) have the following components:

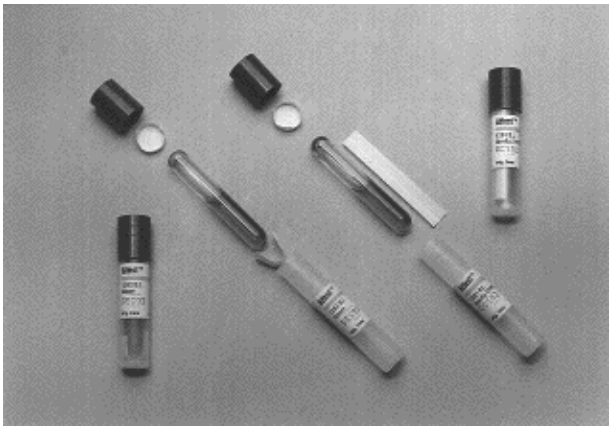
1. Dry spore strips containing spores of *Bacillus stearothermophilus* (derived from ATCC 7953) with a minimum population of 1×10^5 spores per strip.
2. Growth medium contained in a crushable glass ampule. This medium is modified Tryptic Soy broth with a pH-sensitive indicator dye (bromocresol purple).
3. A flexible polypropylene vial to hold both the dry strip and the medium ampule.
4. A blue (1261P) or brown (1262P) polypropylene cap containing a coated hydrophobic filter which is a sterilant-permeable bacterial barrier.
5. A label bearing the date of manufacture of the Attest™ indicator and a process chemical indicator that turns from rose to brown when processed. Space is provided to record test data.

   NOTE: Do not use to monitor dry heat, chemical vapor (MDT Harvey® chemiclave) or ethylene oxide (EO) sterilization processes.

Biological Indicators and Test Packs for Steam Sterilization Monitoring

Load	Temperature	Time (min)	Air Removal Method	Attest™ Biological Indicator	Attest™ Cap Color
Packs Containing Fabric	250-254°F (121-123°C)	≥ 30	Gravity	1262P	Brown
	or				
	270-274°F (132-135°C)	≥ 3	Pulsing Prevacuum		
	or				
	285-287°F (141-143°C)	≥ 2	Pulsing		
Wrapped Hard Goods	250-254°F (121-123°C)	20	Gravity	1262P	Brown
	or				
	270-274°F (132-135°C)	10	Gravity	1261P	Blue
Unwrapped Hard Goods	250-254°F (121-123°C)	≤ 15	Gravity	1262P	Brown
Unwrapped Hard Goods	270-274°F (132-135°C)	≥ 3	Gravity	1261P	Blue
Unwrapped Hard Goods	270-274°F (132-135°C)	≥ 3	Prevacuum Pulsing	1262P	Brown

1262P Indicator



Attest™ Steam Incubator

1261P Attest™ biological indicators were designed to monitor 270°F/132°C gravity "flash" steam sterilization processes. Special spore strip placement and cap design on the 1261P Attest™ biological indicator provide a more representative challenge to the 270°F/132°C gravity displacement steam sterilization cycle.

1262P Attest™ biological indicators were designed to monitor 250°F/121°C gravity, 270°F/132°C prevacuum, or pulsing-steam sterilization processes.

Test Frequency

For optimal sterilization quality assurance it is recommended that Attest™ biological indicators be used in test packs to monitor each load of steam sterilized supplies. (See Addendum for further details).

Testing with biological monitors should be done at least weekly in most dental practices.[2, 9]

Usage of Test Packs

For optimal quality assurance of the sterilization process, an Attest™ biological indicator should be used to monitor every load of steam sterilized supplies. The Attest™ biological indicator should be placed in a test pack that is representative of the load being processed and one that creates the greatest challenge to the sterilization process.[10]

Steam Cycles

Steam test packs are designed to create a challenge to the steam sterilization process.

1. **Unwrapped hard goods**
   a. 250-254°F (121-123°C) for 15 minutes or more in a gravity displacement cycle.

      Place a 1262P Attest™ biological indicator in an unwrapped basin, tray, or any unwrapped metal item that is representative of the load being sterilized.

   b. 270-274°F (132-135°C) for 3 minutes or more in a gravity cycle (e.g., flash cycle).

      Place a 1261P Attest™ 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 instrument tray.[11]

   c. 270-274°F (132-135°C) for 3 minutes or more in a pulsing or prevacuum cycle.

Place a 1262P Attest™ biological indicator in a representative unwrapped hard goods item (e.g., instrument tray) from the sterilizer load.

2. **Wrapped hard goods**

   a. 250-254°F (121-123°C) for 20 minutes in a gravity displacement cycle.

      Place a 1262P Attest™ biological indicator in the center of a representative wrapped hard goods pack (e.g., instrument set) from the sterilizer load. Sacrifice the pack to retrieve the biological indicator.

   b. 270-274°F (132-135°C) for 10 minutes in a gravity displacement cycle.

      Place a 1261P Attest™ biological indicator in the center of a representative wrapped hard goods pack (e.g., basin or instrument set) from the sterilizer load. Sacrifice the pack to retrieve the biological indicator.

   c. 270-274°F (132-135°C) for 3 minutes or more in a pulsing or prevacuum cycle.

      Place a 1262P Attest™ biological indicator in the center of a representative wrapped hard goods pack (e.g., basin or instrument set) from the sterilizer load. Sacrifice the pack to retrieve the biological indicator.

3. **Fabric packs** containing goods run at 250-254 °F (121-123°C) for 30 minutes or more in a gravity displacement cycle, at 270-274°F (132-135°C) for 3 minutes or more in a pulsing or prevacuum cycle, or 285-287°F (141-143°C) for 2 minutes or more in a pulsing cycle.

   a. Place a 1262P Attest™ biological indicator between two small packs from the sterilizer load which, taken together, approximate the largest and most dense pack in that load. Overwrap the packs and label as a test pack. After processing, the indicator can be retrieved without sacrificing the goods.

   b. Place a 1262P Attest™ biological indicator in the center of an actual pack from the sterilizer load which is representative of the goods contained in that load (e.g., a linen pack for a load of linens, a tray for loads which include metal instruments, etc.). Place the 1262 Attest™ biological indicator in the center of the pack. Sacrifice the pack to retrieve the biological indicator.

NOTE: The 1261P Attest™ biological indicator may be placed in a tray or container of medical devices going directly to patient use to ensure that the medical devices are properly sterilized. Remember to aseptically transfer the contents of the tray or container to the sterile field before removing the biological indicator for incubation.

See "Instructions For Use" section for further details.

Validation Testing

Validation testing should be performed on an ongoing basis to periodically evaluate products routinely sterilized.[12,13]

AAMI states that "Product testing should always be done when major changes are made in packaging, product or load configuration, or materials, such as dimensional changes, weight changes, or changes in the type of packaging or wrapper used."[14]

It is also recommended that validation testing be done quarterly, after sterilizer installation, any major redesign or relocation of a sterilizer, or after suspected malfunction or major repair.[15] The facility should run three consecutive cycles resulting in negative biological indicators before the sterilizer is put back into use.

To do validation testing, place multiple 1261P, 1262P Attest™ biological indicators and chemical indicators in the areas of the packaging and load that create the greatest challenge to air removal and steam, or humidity penetration. Do repetitive and thorough testing to determine the sterilization process parameters needed to produce consistent negative biological indicators and chemical indicators with complete end point color changes. The product or sterilizer should not be used until biological indicators are routinely negative.[16]

Validation testing determines the sterilization process parameters needed to produce a sterile medical device when changes are made. Routine testing ensures that sterilization process parameters determined during validation testing are being met on a regular basis. See "Instructions For Use" for further details on how to use Attest™ monitoring products.

Interpretation of Results

1. Examine the indicator at regular intervals (e.g., 8, 12, 18, 24 and 48 hours) for any color change. Appearance of a yellow color (a positive readout) indicates bacterial growth. No color change indicates an adequate sterilization process.
2. Act on any positive test as soon as the first evidence of growth is noted, even if only one Attest™ biological indicator shows a positive when two or more were used in the sterilization cycle.

Always retest the sterilization process by placing several test packs containing Attest™ biological indicators throughout the test load. Attest™ biological indicators can be subcultured if identification of positive growth is desired (See *Disposal* for further details).

3. The recommended incubation time for 1261P Attest™ biological indicators is 24 hours. The recommended incubation time for 1262P Attest™ biological indicators is 48 hours. A final determination of sterility can be made after these stated incubation times.
4. Record results (log books are available).

Instructions for Use

Choose the appropriate biological indicator, and test pack configuration for the sterilization process being used.

1262P Attest™ biological indicators for steam sterilization.

1. Identify the indicator by noting the sterilizer and load numbers, and the processing date on the label.
2. Place a 1262P Attest™ biological indicator in a suitable test pack which is representative of the load. See *Usage of Test Packs* for further details.
3. Place the test pack in a full load in the area most challenging for the sterilant. In a steam sterilizer 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.

   Warning: Crushing or excessive handling of the biological indicators before cooling may cause the glass ampule to burst which may result in personal injury from flying debris. 3M recommends the use of safety glasses and gloves when removing biological indicators from the sterilizer. Safety glasses should also be worn when crushing biological indicators.
6. Retrieve the Attest™ biological indicator from the test pack.
7. Check the chemical indicator on the label for a color change from rose to brown.
8. Incubate the biological indicator within two hours or refrigerate it until incubation is possible. (If these instructions are not followed the spores will die off at room temperature and a

sterilization failure may go undetected.)[17] The incubator temperature is 133 ± 3°F (56 ± 2°C).

1261P Attest™ biological indicators for 270°F/132°C gravity displacement steam sterilization.

1. Identify the indicator by noting the sterilizer and load numbers, and the processing date on the label.
2. Place a 1261P Attest™ biological indicator in a suitable tray which is representative of the load. See *Usage of Test Packs* for further details.
3. Place the tray (e.g., perforated instrument tray with representative instruments on the bottom shelf, near the door, and over the drain) in an otherwise empty load.
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.

   Warning: Crushing or excessive handling of the biological indicators before cooling may cause the glass ampule to burst which may result in personal injury from flying debris. 3M recommends the use of safety glasses and gloves when removing biological indicators from the sterilizer. Safety glasses should also be worn when crushing biological indicators.
6. Retrieve the Attest™ biological indicator from the test tray.
7. Check the chemical indicator on the label for a color change from rose to brown.
8. Incubate the biological indicator within two hours or refrigerate it until incubation is possible. (If these instructions are not followed the spores will die off at room temperature and a sterilization failure may go undetected.)[18] The incubator temperature is 133 ± 3°F (56 ± 2°C).

Use of Controls

As a positive growth control, place a non-sterilized Attest™ biological indicator in each incubator each day Attest™ indicators are used. This control must be of the same lot and manufacturing date as the test biological indicators used that day. The purpose of this 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 medium to promote rapid growth.

When examining the processed indicator at regular intervals such as 8, 12, 18, 24 and 48 hours, also examine the control indicator for a color change toward yellow (evidence of bacterial growth). Record results and discard indicators in accordance with your healthcare facility's policy.

The Attest™ monitoring system provides separate color coded vials for steam indicators. This one spore per vial system provides the user with the best assurance of sterility. If both indicator organisms are on the same spore strip (e.g., as in a two spores per vial system), a positive growth control could be obtained if incorrect incubation conditions existed (e.g., incubator not functioning, or vials inadvertantly incubated at wrong temperature). If the test biological indicator came from a cycle with a sterilization process failure, a false positive control and false negative test would result.[19]

Incubators

The Attest™ system offers a dry block incubator. Each Attest™ incubator is pre-set at the appropriate temperature to promote growth of the test organism. The incubator's internal temperatures are rigidly controlled and automatically maintained.

Attest™ incubators provide optimal conditions for the accurate read-out of the Attest™ indicators. The growth of each test organism is temperature dependent, it is critical that the Attest™ indicators be used with the Attest™ incubator. The system is color-coded for quick, easy identification.

Attest™ dry block incubators with a 14-vial capacity are available for both steam indicators (No. 116 which operates at 110/120 volts and No. 118 which operates at 220/240 volts).

Do not add water to these incubators.

Incubation

Attest™ System for Steam

Attest™ Indicator	Cap Color	Incubation time
1261P	Blue	24 hours
1262P	Brown	48 hours

Instructions for Incubation use

1. Position indicator in metal block (See Figure 1). Place the bottom of the indicator into the incubator's metal heating block so that the indicator is at an angle of approximately 45°.

Figure 1

2. Push the indicator straight back (See Figure 2). This crushes the ampule and activates the indicator.

Figure 2

3. 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 you push the indicator down.

Figure 3

Any positive biological indicator must be considered evidence of an inadequate sterilization process. This evidence must not be ignored, or regarded as a "false positive" test.

Action

1. Retrieve and reprocess all goods run in that sterilizer dating from the last negative biological indicator.[20]
2. Rechallenge the sterilizer with several biological indicators placed in appropriate test packs or trays throughout the load.
3. The sterilizers in question should not be returned to regular service until the results of this retesting are all satisfactory (i.e., negative).

Potential Causes of Sterilization Failure[21,22,23]

It must be remembered that sterilization is a process; a deficiency in any of the variables necessary to effect sterilization can result in nonsterile product. These variables include:

- sterilizer performance
- sterilant quality and quantity
- choice of packaging materials
- packaging technique
- sterilizer loading techniques
- inappropriate cycle parameters for the items being processed.

Checklists of potential causes of steam sterilization failure follow.

Steam Sterilization

The parameters needed for steam sterilization are time, temperature and saturated steam. A steam sterilization process failure can be caused by poor steam quality and/or inadequate steam quantity, equipment mal-function and human error.

- Poor steam quality and/or inadequate steam quantity, caused by:
    1. Wet steam
        - — inadequate trap in steam line
        - — steam contact with a cold load
        - — steam pressure too high for the temperature

2. Superheated steam
   — improper chamber heat up
   — desiccated packaging materials
   — steam pressure too low for the temperature
3. Variations in steam pressure due to clogged filters, poorly engineered piping or excessive demands.
4. Out-of-calibration pressure gauges and controllers.
   a. Incomplete air removal
      — plugged drain screen
      — clogged vent lines
      — faulty vacuum pump
      — inadequate door gasket seal
      — low steam pressure
      — plugged, faulty or maladjusted control valves
      — come up time less than 1.5 minutes
   b. Inadequate cycle temperature
      — temperature gauge out of calibration
      — long heat-up time of large loads (heat lag)
      — variations in steam pressure due to clogged filters, poorly engineered piping or excessive demands on the steam supply
   c. Insufficient time at temperature
      — timer gauge out of calibration
      — inappropriate cycle parameters for the load being processed
      — come up time less than 1.5 minutes
   d. Human error
      — inadequately cleaned items preventing steam penetration
      — packaging materials impermeable to steam
      — packs too large or too dense for the cycle parameters
      — poor loading techniques that entrap air and prevent steam penetration
      — incorrect operation of sterilizer
      — entire load inadvertently not processed

Resistance Data

Biological indicators must provide an adequate challenge to the sterilization process. The resistance of a biological indicator to the mode of sterilization can be defined by several methods. A common resistance measurement is survival/kill data. Survival/kill data establishes the time frame for indicator resistance under a specific set of test conditions: i.e., all indicators must survive the given "survival" time and all must be killed by the given "kill" time.

Survival/kill data for Attest™ biological indicators outside of test packs is:

Attest™ Indicator	Test Conditions	Survived	Kill
1261P	Saturated steam @ 270°F (132°C) gravity displacement (Flash) sterilization with 1.5 minute come up time	1 min	3 min.
1262P	Saturated steam @ 250°F (121°C), gravity displacement sterilization	5 min	15 min.
1262P	Saturated steam @ 270°F (132°C), prevacuum sterilization	1 min	3 min.

Subculturing Techniques

If the healthcare facility's policy requires subculturing of all positive biological indicators it is important to subculture the Attest™ biological indicator as soon as it turns positive (preferably within 24 hours after the indicator is incubated). If more than 24 hours pass, the bacteria may die off because of the acid produced during the growth process and viable bacteria will be undetectable.

The procedure for subculturing should first be tried on a positive control to allow the laboratory to become familiar with the subculturing method.

An outline of the subculturing procedure follows. These steps are designed to minimize the chance of contamination.

1. Carry the Attest™ biological indicator in an **upright** position to the laboratory for evaluation.
2. In a clean area (laminar air flow hood), carefully remove the Attest™ biological indicator cap with a twisting motion and then, with a sterile pipette, aseptically remove the contents of the vial.
3. Place one drop of media on a slide and perform a gram stain.
4. Deposit the remaining contents of the pipette into sterile Soybean Casein Digest Broth (SCDB).

5. Incubate the broth at a temperature of 133 ± 3°F (56 ± 2°C) for 1261P or 1262P Attest™ biological indicators. It is critical that the correct temperature be used to ensure the growth of *B. stearothermophilus* (1261P or 1262P Attest™ biological indicators).
6. A bacterial isolation can then be performed by streaking a loopful of the SCDB growth onto prepared Soybean Casein Digest Agar (SCDA) plates and incubate at the appropriate temperature.
7. Perform a gram stain from the growth obtained on the SCDA plate. Also, additional biochemical and morphological determinations can be made to confirm the presence of *B. stearothermophilus* ATCC 7953 or (An "Attest™ Subculturing Reference Sheet" is available from 3M Technical Service.)
8. The gram stain should show gram positive rods.

Storage and Shelf Life

Store Attest™ biological indicators at normal room conditions: 59-86°F (15-30°C), 35-60% relative humidity.

Do not store these indicators near sterilants or other chemicals.

Attest™ biological indicators have a 2-year shelf life from the date of manufacture. The manufacturing date is printed on the label of each biological indicator, and on each box of Attest™ biological indicators.

Disposal

Dispose of used Attest™ biological indicators in accordance with your healthcare facility's policy. You may wish to autoclave any positive indicators at 250°F (121°C) for at least 15 minutes, at 270°F (132°C) for 10 minutes in a gravity steam sterilizer, or at 4 minutes in a pulsing or prevacuum steam sterilizer.

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Addendum

Organizations' Recommendations on Biological Indicators

Organization	Biological Indicator Requirements	Frequency of Use Steam	Quarantine Until Biological Results Available?	Subculture Positive BI's?
AAMI[1] Good Hospital Practice: Steam Sterilization & Sterility Assurance, 1988	Should be used inside a 16 towel or 12" x 12" x 20" hetergeneous test pack.	At least weekly, preferably daily, each load that contains an implantable devices.	Implantable objects if possible.	Should perform a presumptive identification. of the microorganism.
Good Hospital Practice: Steam Sterilization Using the Unwrapped Method (Flash Sterilization), 1986	Should be used in a perforated or mesh bottom tray.	At least once a week (do not flash implantables).	—	A presumptive Identification. should be performed.
ADA[2] Infection control recommendation for the dental office & the dental laboratory, 1992.	Should be placed in packs, bags or tray.	Weekly	—	—
ASHCSP Recommended Practice for Central Service, Sterilization, Oct. 1989	Should be used inside a 16 towel pack for steam.	At least once a day, each load of implantable items.	Implantable items until BI results are available	—
AORN[3] Recommended Practices/Sterilization, and Disinfection, 1990	Should be used in a 12" × 12" × 20" hetergeneous test pack for steam .	Weekly and as needed; each load containing implantables.	Implantable objects until BI is negative at 48 hours.	—
Army Army Regulations (AR40-19), 1984	Shall be used	Minimum of once weekly.	—	—
CDC[4] Recommendedd Infection Practices for Dentistry, 1993	Should be used	At least once a week.	—	—
JCAHO[5] Scoring Guidelines, 1988	Are used	At least weekly, or with each load if sterilization activities are performed less frequently. It is recommended that such test be performed daily and each load of implantables of intravascular material.	Implantable or intravascular material.	—
VA[6] VA Manual 61, MP-2, 1985 and MP-2, Subchapter E, Change 159, June 22, 1983	Must be used in a 12" x 12" x 20" heterogeneous test pack.	Daily. Each load of implantable or intravascular materials.	Implantable or intravascular materials until spore test is negative at 48 hours.	Should do a presumptive identification.

1. AAMI–Association for the Advancement of Medical Instrumentation
2. ADA –American Dental Association
3. AORN–Association of Operating Room Nurses
4. CDC–Centers for Disease Control
5. JCAHO–Joint Commission on Accreditation of Healthcare Organizations.
6. VA–Veteran's Administration

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Dental Products Laboratory

3M Center, Building 260-2B-13
St. Paul, MN 55144-1000

Printed in U. S. A.