3M™ Attest™ 1292E Rapid Readout Biological Indicator

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Introduction

The 3M™ Attest™ 1292E Rapid Readout Biological Indicator Monitoring System is a convenient, reliable biological system for monitoring all steam sterilization processes. This biological monitoring system is a critical component of a quality improvement process which ensures that medical devices are correctly sterilized, ready to use, and meet customer expectations.

The Attest rapid readout steam monitoring system includes a 3M™ Attest™ 1292E Rapid Readout Biological Indicator, the 3M™ Attest™ 190 Auto-reader and log book.

The unique self-contained design of the biological indicator makes it easy to use in the department where the sterilizers are located.

The Attest rapid readout steam monitoring system provides reliable, real-time results that allow a health care facility to detect and respond to sterilization process failures more quickly and efficiently.

In fact, the results are so fast that every load, especially critical medical devices, can be monitored and quarantined until the biological indicator results are available. This means no recalls of potentially nonsterile packages, no need to inform physicians about the use of nonsterile medical devices, and no recall-associated department credibility problems. This also ensures that current accepted practice guidelines on sterilization process monitoring that require quarantining of implantables are met.[6,7,10,11]

Rapid Readout Steam Technology

The 3M™ Attest™ 1292E Rapid Readout Biological Indicator for steam sterilization contains a standardized, viable population of *Bacillus stearothermophilus* ATCC 7953 spores that meet the AAMI, ISO, and EN definition of a biological indicator.[2,4,5,8,9] The biological indicator identifies a sterilization process failure by providing a fluorescent readout within three hours of incubation instead of the 48 hours needed for the visual color change readout used in the 3M™ Attest™ 1262E Biological Indicator.

The visual color change method detects acid metabolites produced during growth of the *Bacillus stearothermophilus* ATCC 7953 spore. The acid metabolites are the result of a series of enzyme-catalyzed reactions that occur during the growth of spores. This growth produces a pH change in the medium. This pH change causes the medium to visually change from purple to yellow. This visual color change indicator is also included in the Attest 1292E rapid readout biological indicator system.

The fluorescent readout of the Attest 1292E biological indicator detects the activity of alpha-glucosidase, a naturally occurring enzyme which is an integral component of the *Bacillus stearothermophilus* spore and involved in spore growth and cell function.[1] The presence of active alpha-glucosidase is measured by a non-fluorescent substrate, 4-methylumbelliferyl-alpha-D-glucoside. The non-fluorescent substrate is converted by the active spore-associated enzyme, alpha-glucosidase, to a fluorescent product, 4-methylumbelliferone. The conversion is illustrated in Figure 1.

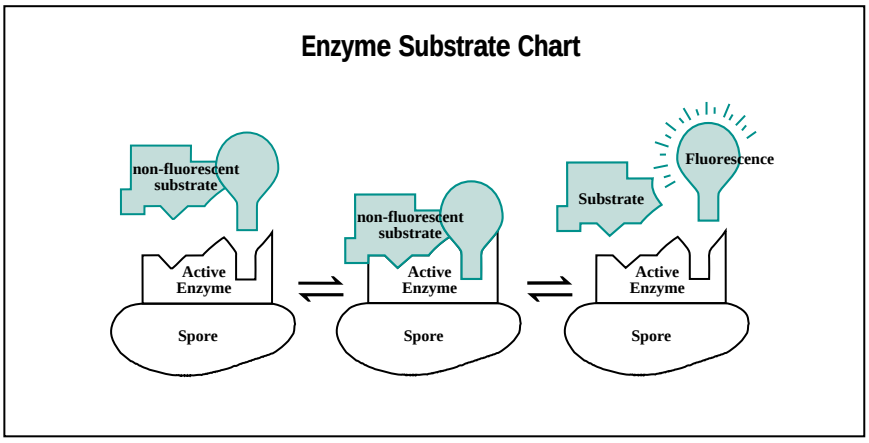


Figure 1

The rapid readout biological indicator system requires both incubation and growth media in order to provide the three-hour final negative biological indicator readout result. No further incubation is required. If a negative reading (i.e., no fluorescence) is obtained after three hours of incubation, NO viable spores are present.

Figure 2, on page 3, shows how the dual indicator system of the rapid readout biological indicator detects a steam sterilization process failure and an acceptable steam sterilization process. In a steam sterilization process failure, both the spores and the spore-associated enzyme remain active. The active spore-associated enzyme converts the non-flourescent

substrate to a fluorescent product that is detected in the Attest auto-reader within three hours of incubation at 60°C. The presence of fluorescence is indicated by a red (“+”) light on the auto-reader. With additional incubation of the biological indicator at 60°C, the spore outgrowth produces a visual color change (purple to yellow) in the growth medium.

In an acceptable steam sterilization process, both the spores and spore-associated enzyme are inactivated. The non-active, spore-associated enzyme does not convert the non-fluorescent substrate to a fluorescent product. Fluorescence is not produced after three hours of incubation at 60°C and the green (“-”) light on the auto-reader is lit. With additional incubation of the rapid readout biological indicator at 60°C, the spores will not grow. Since acid metabolites are not formed, the pH of the medium does not change and the pH indicator remains purple.

The three-hour rapid readout (fluorescence) detection method of the Attest 1292E rapid readout biological indicator is as reliable as the 48-hour visual detection (pH color change) method of the Attest 1262E biological indicator. Both the fluorescent and visual color change readouts are products of reactions indicating biochemical activity of the organisms. Both are reliable methods for detecting steam sterilization process failures.

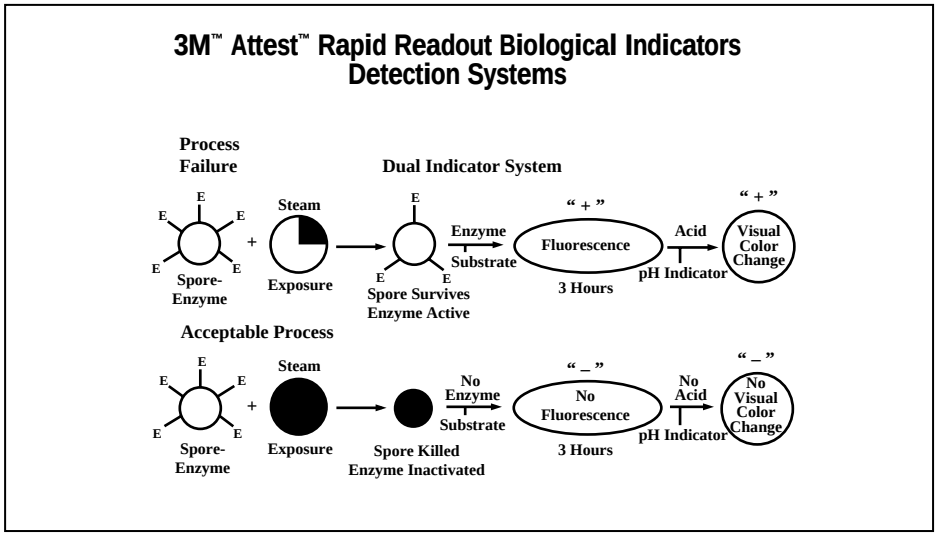


Figure 2

Interpretation of Fluorescent versus Visual Color Change Readout

The Attest auto-reader detects the presence of an active *Bacillus stearothermophilus* ATCC 7953 spore-associated enzyme by reading a fluorescent product that is produced when the *Bacillus stearothermophilus* ATCC 7953 spore-associated enzyme converts the non-fluorescent substrate, 4-methylumbelliferyl-alpha-D-glucoside, in the media vial. The fluorescence indicates the presence of active spore-associated enzyme and a sterilization process failure. Non-fluorescence indicates inactivation of the spore-associated enzyme and a correct sterilization process.

Table 1 shows spore and spore-associated enzyme survival for a lot of Attest 1292E rapid readout biological indicators in a 121°C, vacuum assisted steam sterilizer. The spore-associated enzyme is inactivated and the spores are killed after 15 minutes of exposure. At 14 minutes, 70% of the spore-associated enzyme is still active but only 5% of the spores survived. At 15 minutes, all the spore-associated enzyme is inactivated and all the spores are killed.

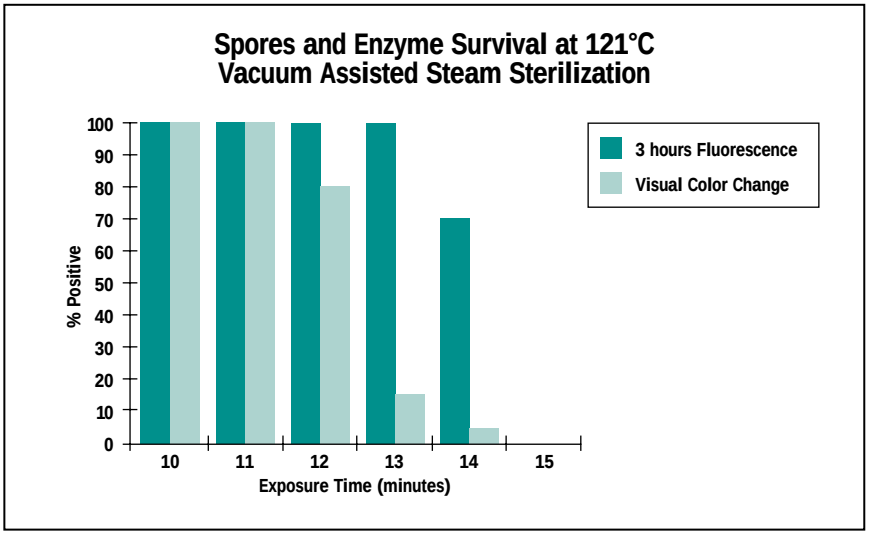


Table 1

Table 1 also demonstrates that the biological activity of the spore-associated enzyme remains active in the steam sterilization cycle longer than the spore. If the steam sterilization process is inadequate or marginal, the enzyme could survive when the spore is unable to grow. Therefore, the active spore-associated enzyme provides a more sensitive indication of an inadequate or marginal sterilization process than the outgrowth
of spores.

The difference between the enzyme and spore response in a marginal steam sterilization process is illustrated in Figure 3. A fluorescent-positive is detected within three hours of incubation, but no visual pH color change is detected. The fluorescent-positive should be regarded as a sterilization process failure and the appropriate action taken (see Positive Biological Indicator on page 11).

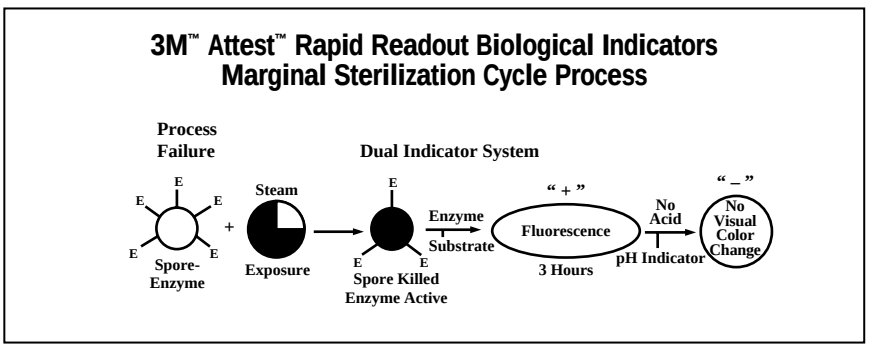


Figure 3

Performance Data

Population, D-values, 10-Rule, Z-Values, Survival and Kill Time

Attest 1292E rapid readout biological indicators meet International Standards (ISO 11138, Part 1 and 3) and European Standard (EN 866, Part 1 and 3).[4,5,8,9]

3M™ Attest™ 1292E Rapid Readout Steam Biological Indicators Performance Data

Performance Criteria	ISO 11138 and/or EN 866, Part 1 and 3 Standard Requirements	Attest 1292E Typical Values*
Population	Not less than 1 x 10^5 cfu (colony forming units)/strip	5 x 10^5 –5 x 10^6 cfu (colony forming units)/strip
121°C D-values	Not less than 1.5 minutes	1.5–2.2 minutes
10-Rule Log_{10} of Population times D-value	Not less than 10	10–14
Z-values	Not less than 6°C	10–13°C
Survival Time	Not less than the (D-value) x (log_{10} Population - 2)	7–10 minutes
Kill Time	Not more than the (D-value) x (log_{10} Population + 4)	16–23 minutes

Table 2

*Typical values represent what was seen when the performance testing was done. Actual values printed in the certification card may vary slightly from the typical value range provided but will meet the requirements of the ISO and EN standards.

Readout Reliability

Readout reliability testing is performed to establish the shortest incubation time necessary to ensure the highest degree of confidence for detecting a sterilization process failure. The minimum incubation time is the time which has the fewest number of false-negative biological indicators (i.e., spore survival without enzyme activity).

Figure 4 illustrates a false-negative result. A fluorescent-negative readout is detected after three hours of incubation at 60°C, but growth is detected by a visual pH color change after 168 hours (seven days) of incubation. The growth-positive should be regarded as a steam sterilization process failure and the appropriate action taken.

False-Negative Biological Indicator Result with the Fluorescent Indicator

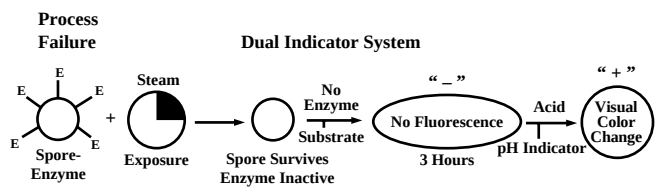


Figure 4

Sensitivity is the statistic used to calculate the readout reliability. With Attest 1292E rapid readout biological indicators, the sensitivity is a measure of the accuracy of the Attest rapid readout monitoring system to indicate spore survival following a steam sterilization process failure. The minimum incubation time for a reliable readout will have a minimum number of false-negatives and a calculated high sensitivity.

The Attest 1292E biological indicators were exposed to partial exposure times in 121°C gravity, 121°C vacuum and 134°C vacuum steam cycles to yield between 30%–80% growth-positives after 168 hours (seven days) of incubation.

With this approach, the level of surviving spores in a biological indicator is extremely low. The low level of surviving spores represents the greatest challenge for determining the reliability of the biological indicators readout time. The reliability is calculated based on the number of growth-positive biological indicators detected after 168 hours of incubation compared to the number that were detected at shorter incubation times (i.e., three hours). Incubation for 168 hours (seven days) provides adequate time to allow all surviving spores to grow and produce a visual color change.

The difference between the number of positive biological indicators after 168 hours (seven days) and the shorter incubation times are called false-negatives. The sensitivity is the number of false-negatives, divided by the number of growth-positives after 168 hours, multiplied by 100.

$$\text{Sensitivity} = \frac{(\text{Number of Growth-Positives after 168 Hours} - \text{Number of False-Negatives})}{\text{Number of Growth-Positives after 168 Hours}} \times 100$$

3M™ Attest™ 1292E Rapid Readout Biological Indicators
121°C Gravity Displacement, 121°C and 134°C Vacuum Assisted
Steam Sterilization Process Readout Reliability Summary

Sterilization Process	Incubation Temperature	Number Tested	Number Growth-Positives 168 HR	False-Negatives 2 HR	False-Negatives 3 HR	Sensitivity 2 HR	Sensitivity 3 HR
121°C Gravity Displacement	60°C	1600	488	0	0	100	100
121°C Vacuum Assisted	60°C	1737	531	61	0	88.5	100
134°C Vacuum Assisted	60°C	2740	442	1	0	99.8	100

Table 3

This data shows that the three-hour fluorescent sensitivity of Attest 1292E rapid readout biological indicators is ≥ 97% based on the number of visual growth-positives after 168 hours (seven days) incubation at 60°C.

The data shows that all the 168 hour (seven day) growth-positives were detected by fluorescence within three hours of incubation. This means no false-negative biological indicators were detected after three hours of incubation. This also means that if there is no fluorescence at three hours, no growth-positives will be detected if incubation continues.

Based on the claimed ≥ 97% readout reliability of the three-hour biological indicator results, there is no advantage to incubating Attest 1292E rapid readout biological indicators beyond three hours.

Product Description

Biological Indicators

The Attest rapid readout steam monitoring system includes the Attest 1292E rapid readout biological indicator, Attest 190 auto-reader and log book. These are designed to ensure optimal reliability and assist a health care facility in improving the performance of the steam sterilization process. All Attest biological indicators are self-contained (i.e., contain both the dry spore strip and the growth medium). The one spore strain per vial design provides information about the incubation and sterilization process that may not be obtained with a two spore strain per vial design.

The Attest rapid readout biological indicator monitoring system is a convenient, reliable biological system for monitoring all steam sterilization processes. It meets all biological monitoring requirements suggested by:

- The Association for the Advancement of Medical Instrumentation (AAMI),[6]
- The Joint Commission on Accreditation of Healthcare Organizations (JCAHO),[3]
- The Association of Operating Room Nurses (AORN),[11]
- The American Society for Healthcare Central Service Professionals (ASHCSP).[10]

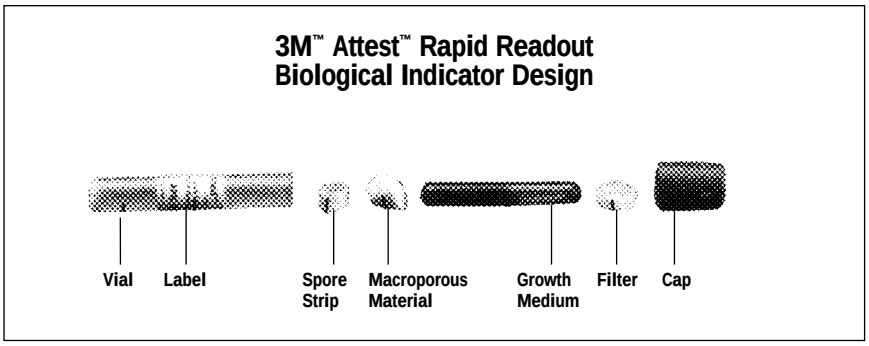


Figure 5

The Attest 1292E rapid readout biological indicators have the following components:

- Dry paper spore strip containing at least 5 x 10^5 spores per strip of *Bacillus stearothermophilus* ATCC 7953.
- Growth medium contained in a crushable glass ampule. The medium is a modified tryptic soy broth with a dual indicator system. One indicator is a non-fluorescent substrate, 4-methylumbelliferyl-alpha-D-glucoside, and the other is a pH-sensitive indicator dye, bromocresol purple.
- Non-woven polypropylene macroporous materials to help concentrate the fluorescence at the bottom of the formed polypropylene vial.
- A flexible polypropylene vial holds both the dry spore strip and the glass ampule of medium.
- A brown polypropylene cap containing a coated hydrophobic sterilant-permeable filter.
- A label which provides space to record test data. It bears the date of manufacture and a process chemical indicator that turns brown when steam processed.

Indications

Use the Attest 1292E rapid readout biological indicator to monitor:

- 121°–134°C vacuum assisted steam sterilization cycles
- 121°–123°C gravity steam sterilization cycles

Contraindications:

Do not use the Attest 1292E rapid readout biological indicator to monitor:

- 132°–135°C gravity steam sterilization cycles
- Dry heat, chemical vapor, ethylene oxide or other low temperature sterilization cycles

Auto-reader

The Attest 190 auto-reader provides appropriate incubation temperature and quick, accurate fluorescent readout of Attest 1292E rapid readout biological indicators. The reader is color-coded with brown to match the Attest 1292E biological indicator cap color.

3M™ Attest™ Auto-readers for use with the 3M™ Attest™ 1292E Rapid Readout Biological Indicators Temperature: 60°± 2°C

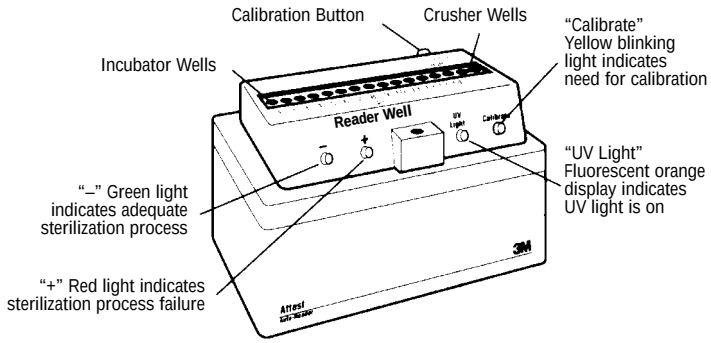
Model Number	Nominal Voltage	Country
190J	110	Japan only
190	120	North America, etc.
193	230	Europe, etc.
191	240	Australia only

Table 4

The Attest 190 auto-reader is designed to read the fluorescence produced by positive Attest 1292E rapid readout biological indicators. It detects the presence of an active *Bacillus stearothermophilus* ATCC 7953 spore-associated enzyme, alpha-glucosidase, by reading a fluorescent product that is produced when the enzyme converts the non-fluorescent substrate, 4-methylumbelliferyl-alpha-D-glucoside, in the media vial. The fluorescence indicates the presence of active *Bacillus stearothermophilus* ATCC 7953 spore-associated enzyme and a steam sterilization process failure. Non-fluorescence indicates inactivation of the enzyme and an adequate steam sterilization process. A sterilization process failure is observed by a red light (“+”). An adequate sterilization process is observed by a green light (“-”).

For more details on the use of the Attest auto-reader see the operating instructions included with each unit.

3M™ Attest™ Auto-reader Diagram



Appropriate Use of Biological Indicators

Biological indicators are used for load control monitoring to determine the effectiveness of the sterilization process and to release medical devices for use. Monitor every steam load, especially critical medical devices, with an Attest rapid readout biological indicator placed in an appropriate test tray or package to improve the sterilization process. Quarantine the load and release medical devices when the biological indicator is negative. Quarantining and every load biological indicator monitoring are the most practical and least expensive operational processes that also meet your ethical responsibilities to the patient.[12]

Test Frequency

In addition to every load monitoring, biological indicator testing should be done whenever a sterilizer is installed, relocated, redesigned, and after preventive maintenance. Run three consecutive empty cycles with a biological and chemical indicator in an appropriate test pack.[6] Biological indicator testing is also required whenever a change is made that affects any part of the sterilization process. This product testing involves placing biological and chemical indicators in products, processing the load, opening the products, retrieving the indicators, and reading and recording the indicator results. The procedure should be repeated two more times.[6] When three consecutive cycles show negative biological indicators and chemical indicators with a correct end point response, for the above testing, the sterilizer and the product change is put into routine use.

Appropriate Test Packs

The Attest rapid readout biological indicator should be placed in a test package that is representative of the load being processed and creates the greatest and most appropriate challenge to the sterilization process.

Positive Controls

A positive control should be incubated each day a sterilized vial is incubated or every time the auto-reader is calibrated. The test results are not valid until the positive control shows a red light (“+”). It is good practice to incubate the positive control for a visual color change. This helps ensure:

- correct incubation temperatures are met,
- viability of spores have not been altered due to improper storage temperature, humidity or proximity to chemicals,
- capability of media to promote rapid growth, and
- proper functioning of auto-reader components.

Storage and Shelf Life

Store Attest rapid readout biological indicators under normal room conditions: 15–30°C, 35–60% relative humidity.

Do not store these biological indicators near sterilants or other chemicals.

Attest rapid readout biological indicators have a two-year shelf life.

The lot in a box and the hourglass symbols represent lot number and expiration date. The hourglass is followed by a year and month which represent the expiration date (year and month: 2000-10). The entire line after the hourglass represents the lot number (2000-10 AZ).

Disposal

Dispose of used Attest rapid readout biological indicators according to your health care facility's policy. You may wish to sterilize any positive biological indicators prior to disposal.

Positive Biological Indicators

Any fluorescent-positive result at three hours must be considered evidence of a sterilization process failure. This evidence must not be ignored or regarded as a "false-positive" test.

NOTE: Test vials in which the medium dries up or turns brown are not considered positive but invalid. Discard the vial and retest.

Suggested Action Steps[6,13]

1. Report the positive biological indicator results to your supervisor.
2. Recall all medical devices processed in that sterilizer since the last negative biological indicator was obtained. Call the departments and tell them which medical devices to recall. The information needed by the departments for recall is the load information—sterilizer number, load number, and processing date.
3. Quarantine all recalled medical devices until completion of the investigation, then reprocess.
4. Notify infection control so that follow-up surveillance of patients can be conducted, if need be, as determined by the health care facility's policy.
5. Subculture the biological indicator if you suspect it was not correctly activated and incubated.
6. Try to determine the cause of the sterilization process failure. Check monitoring controls from cycles before and after the load, the correctness of the biological indicator and test pack for the load, sterilizer performance, sterilant quality and quantity, packaging and loading technique, appropriate cycle parameters for the load and relative humidity in the processing area.
7. Correct the identified problem. Retest the sterilizer before returning to routine use. Run a biological indicator test pack in three consecutive empty cycles. Place the sterilizer into routine use if all results indicate the sterilizer is functioning properly.

Suggested Action Steps (continued)

8. Provide a written report.
9. When the sterilizer is placed back into service, test each load with an appropriate test pack or tray. If more positive results occur, re-check the sterilant quality and quantity, packaging and loading technique, appropriate cycle parameters for the load, and relative humidity in the processing area for errors.

Potential Causes of Steam Sterilization Process Failures

It must be remembered that steam sterilization is a complex process; a deficiency in any of the variables necessary to effect sterilization can result in a nonsterile medical device.

These variables include:

- sterilizer performance
- steam quantity and quality
- preconditioning of medical devices in the processing area and the sterilizer
- choice of packaging materials
- packaging technique
- sterilizer loading technique
- cycle parameters chosen for the load being processed
- biological indicator test pack chosen for the load being processed

A checklist with potential causes of steam sterilization process failures is provided below.

The parameters needed for steam sterilization are time, temperature, and saturated steam. Poor quality or quantity of steam, equipment malfunction and human error can cause a steam sterilization process failure.

Poor Steam Quality and Quantity, Caused by:

Non-condensable gases (NCG)

- ☐ improperly or untreated boiler feed water
- ☐ improperly or non-degassed boiler feed water
- ☐ venturi leaks

Wet steam

- ☐ improperly insulated steam lines
- ☐ inadequate trap in steam line
- ☐ steam contact with a cold load
- ☐ steam pressure too high for the temperature
- ☐ too much water in steam produced at boiler

Superheated steam

- ☐ improper chamber heat-up
- ☐ desiccated packaging materials (e.g., towels)
- ☐ steam pressure too low for the temperature
- ☐ purging steam prior to pressure reducing valve

Potential Causes of Steam Sterilization Process Failures (continued)

- ☐ variations in steam pressure due to clogged filter, poorly engineered piping or excessive demands
- ☐ pressure gauges and controllers out of calibration

Incomplete Air Removal

- ☐ plugged drain screen
- ☐ clogged vent line
- ☐ inadequate door gasket seal
- ☐ low steam pressure
- ☐ plugged, faulty or maladjusted control valves

Inadequate Cycle Temperature

- ☐ temperature gauge out of calibration
- ☐ insufficient preheat time for large loads (i.e., heat lag)
- ☐ variations in steam pressure due to clogged filter, poorly engineered piping or excessive demands on the steam supply
- ☐ presence of non-condensible gases in steamline and load

Insufficient Time at Temperature

- ☐ timer gauge out of calibration
- ☐ inappropriate cycle parameters for the load being processed

Incorrect Choice of Packaging or Packaging Technique

- ☐ using solid instead of perforated or mesh bottom metal trays
- ☐ using inappropriate packaging materials for the cycle parameters

Human Error

- ☐ inadequately cleaned medical devices which prevent sterilant penetration
- ☐ not disassembling medical devices so the sterilant can penetrate
- ☐ packaging materials impermeable to steam
- ☐ packs too large or too dense for the cycle parameters
- ☐ poor loading techniques that inhibit steam penetration
  - ☐ stacking metal trays or containers on top of each other
  - ☐ stacking peel pouches on top of each other
- ☐ entire load inadvertently not processed
- ☐ inappropriate cycle parameters for the medical devices being processed
- ☐ inappropriate biological indicator test pack for the load
- ☐ incorrect operation of sterilizer

Subculturing Techniques

If the health care facility's policy requires subculturing of positive biological indicators, the following protocol may be used to subculture Attest biological indicators.

Directions for Subculturing

Incubate the fluorescent-positive biological indicator until the media turns yellow. If the subculturing procedure is attempted more than 24 hours after the medium turns yellow, the acid produced during the growth of the organism may kill the surviving bacteria, so no organisms will be recovered. Do not try to subculture a vial in which the medium is dried up or a vial in which the medium has not turned yellow; the population of organisms may be too low to recover.

The procedure for subculturing should first be tried on a positive control to allow the laboratory to become familiar with the subculturing method. A positive control should always be run in parallel with a positive test to demonstrate that reagents, media or incubation conditions are correct to detect *Bacillus stearothermophilus*.

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

1. Transport the Attest rapid readout biological indicator in an upright position to the laboratory for evaluation.
2. In a laminar flow hood or equivalent clean environment, carefully pull the Attest biological indicator cap off with a twisting motion.
3. Aseptically mix the medium with a sterile pipette and remove the contents.
4. Place one drop of medium on a slide and perform a gram stain for presumptive identification. *Bacillus stearothermophilus* will appear as a Gram-positive rod. If anything other than a Gram-positive rod is observed this would be indicative of contamination. No further culturing is necessary unless you want to specifically identify the species of the organism.
5. To identify the species of the organism, transfer the rest of the medium to Trypticase Soy Agar (TSA) or Sheep Blood Agar (SBA) and streak for isolation.
6. Incubate the agar plate at a temperature of 56 ± 2°C for 24–48 hours. It is critical that the correct temperature be used to ensure the growth of *Bacillus stearothermophilus.* Perform gram stain, biochemical and morphological tests to confirm the species.

References

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4. *European Standard EN 866 Biological systems for testing sterilizers and sterilization processes—Part 1: General requirements.* European Committee for Standardization, 1997.

5. *European Standard EN 866 Biological systems for testing sterilizers and sterilization processes—Part 3: Particular systems for use in moist heat sterilizers*. European Committee for Standardization, 1997.

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11. *Recommended Practices for Sterilization in the Practice Setting.* AORN, 1999.

12. Ross, Edwin S. Using Biological Monitoring to Reduce Infection, Risk, and Costs. *Surgical Services Management*, Volume 4, Number 7, July 1998: 37–41.

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Addendum

Sterilization Process Monitoring Accepted Practices for Load Control

Organization	Biological Indicator Requirements	Frequency of Use		Quarantine Until Biological Results Available	Subculture Positive BIs?
		Steam	EO		
AAMI[1] Good Hospital Practice: Steam Sterilization & Sterility Assurance, 1993	Should be used inside a 16-towel test pack.	At least weekly, preferably daily, each load that contains an implantable device. Ongoing QA, after changes, installation, repair.	—	Implantable devices until BI results available.	A presumptive identification should be performed.
AAMI[1] Steam Sterilization & Sterility Assurance in Office-Based Ambulatory - Care Medical and Dental Facilities, 1992	Should be used in representative package or tray.	At least weekly preferable daily, each load that contains implantable device. Installation testing, after major repair.	—	Whenever possible implantable devices until BI results available.	A presumptive identification should be performed.
AAMI[1] Flash Sterilization—Steam Sterilization of Patient Care Items for Immediate Use, 1996	Should be used in a perforated or mesh bottom tray, single-wrapped tray; protective case; rigid container.	At least weekly, preferably daily, (loads containing implantable devices) Ongoing QA, after changes, installation, repair.	—	—	A presumptive identification should be performed.
AAMI[1] Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness, 1999	Should be used in a syringe/towel pack.	—	Each cycle, ongoing QA, after changes, installation, repair.	Implantable objects "whenever possible" until BI results available.	A presumptive identification should be performed.
ASHCSP[2] Recommended Practice for Central Service, Sterilization, 1995	Should be used inside a 16-towel pack for steam. A syringe pack for EO.	At least once a day, each load of implantable items, departure from normal operation.	Each load, departure from normal operation.	Implantable items until BI results are available.	—
AORN[3] Recommended Practices for Sterilization in the Practice Setting, 1999	—	Daily and with each load containing implantables, when evaluating sterilization of new items, after sterilizer installation, major repair, major redesign or relocation.	With every load.	—	—
CDC[4] Guidelines for Handwashing and Hospital Environmental Control, 1985	Should be used.	At least once a week and each load if it contains implantable objects.	At least once a week and each load if it contains implantable objects.	Implantable objects until BI results are negative.	—
JCAHO[5] Comprehensive Accreditation Manual for Hospital, 1999	Policies and procedures should be based on the most stringent recommended practices, laws, regulations and current scientific knowledge.			—	—
VA[6] Handbook 7176	—	Daily, each load containing an implantable device, after major repair.	Each cycle.	—	—

1. AAMI—Association for the Advancement of Medical Instrumentation
2. ASHCSP—American Society for Healthcare Central Service Professionals
3. AORN—Association of Operating Room Nurses
4. CDC—Centers for Disease Control and Prevention
5. JCAHO—Joint Commission on Accreditation of Healthcare Organizations
6. VA—Department of Veteran's Affairs

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