3M | Attest™
Sterilization Solutions

STEAM

3M™ Attest™ Steam Chemical Integrator

Dynamics of Steam Sterilization

Steam sterilization has been used for over 100 years. Decades of research have shown that the efficacy of a steam sterilization process is the function of three basic parameters: time, temperature and the presence of saturated steam. All three are critical process variables for effective steam sterilization.

The importance of saturated steam is demonstrated when dry heat sterilization is compared with steam sterilization. The use of steam allows faster sterilization than dry heat. For example, dry heat sterilization requires a sterilization time of 60 minutes at 320°F (160°C), while steam sterilization at the same temperature would take less than a minute.[1] Clearly, steam quickens the kill time of living organisms by many orders of magnitude and is generally preferable to dry heat.

Once a saturated steam environment is obtained, the independent variables of time and temperature can be determined by the following formula:[2]

$t = F_o \times 10^{(250-T)/Z}$

Where

t = time for 100% kill at temperature T

T = processing temperature (0°F)

F_o = kill time for *Geobacillus stearothermophilus* with a z-value of 18°F (10°C) and D-value of 1 minute at 250˚F (121˚C)

z = rise in temperature required to increase the rate of kill by a factor of 10 (usually about 18˚F (10˚C))

Interpretation of this formula shows that the relationship of processing time (t) versus temperature (T) can be plotted as a logarithmic function. Expressed differently, it means that a small fluctuation in the temperature results in a large change in the actual processing time required for 100% kill. Figure 1 shows the thermal death time at different temperatures for 1 million live spores of *Geobacillus stearothermophilus*.[3] This curve can be expressed mathematically by the following formula which shows that it takes 12 minutes to kill 1 million living spores in a 250°F (121°C) steam sterilization cycle.

$t = (12)10^{(250-T)/18}$

Where

F_o = 12 min for *G. stearothermophilus*

z = 18°F (10°C) for *G. stearothermophilus*

In order to show the high sensitivity of kill time to temperature, the above formula can be solved for 247°F (119°C).

$t = (12)10^{(250-247)/18}$

$t = (12)10^{(0.167)} = (12)(1.47)$

t = 17.6 minutes

In theory, therefore, if the inside temperature of a sterilizer were actually operating at 247°F (119°C) instead of 250°F (121°C), a time of 17.6 minutes would be required to kill the 1 million spores of *G. stearothermophilus* at 247°F (119°C) versus the 12 minutes needed to kill the spores at 250°F (121°C).

This interdependence of time and temperature (in saturated steam) is an important relationship which should be understood by all personnel responsible for providing sterility assurance for steam sterilized items. Consider the ramifications if a sterilizer was inadvertently set at a processing temperature at 247°F (119°C) instead of 250°F (121°C). Or, if the load was processed at 247°F (119°C) as a result of a minor malfunction of the sterilizer (e.g., air pocket or small air leak), a slight calibration error or a natural drift in the temperature monitoring system, incorrect loading or packaging.

Because even small decreases in temperature during steam sterilization may significantly increase the time necessary for assurance of sterility, an accurate means of monitoring internal sterilizer and pack conditions are essential.

Integrating Indicator vs. Biological Death Curve

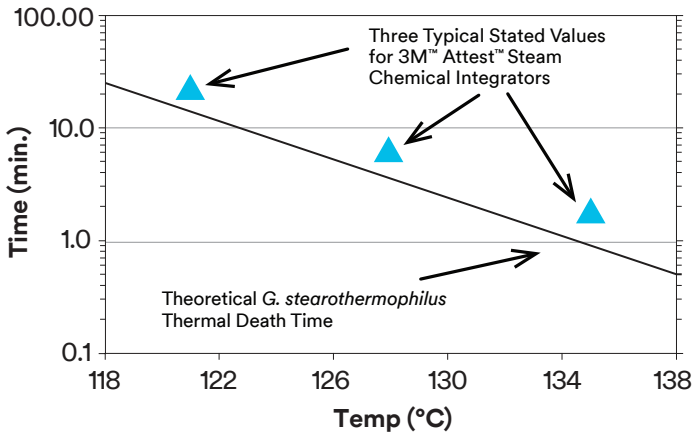


Figure 1. Graph comparing three typical Stated Values of 3M™ Attest™ Steam Chemical Integrators with the theoretical death curve of *Geobacillus stearothermophilus* spores.

Pack and Load Control

The dynamics of steam demonstrate the need for accurate monitoring of internal sterilization conditions. Pack control is the use of chemical indicators for the internal monitoring of packs, trays, containers, and peel pouches. Internal chemical indicators should be used inside each type of packaging to address the potential for interference with proper steam sterilization conditions in all of these types of packaging.[4,5,6]

Several problems can occur in the packaging and loading of individual packs that can inhibit air removal and steam penetration which leads to a lower temperature. Packing problems include:

- Incorrect packaging or container system chosen for the cycle parameters;
- Incorrect preparation of the container for use (i.e., filters and valves or inappropriate bottom tray);
- Placing a folded peel pouch inside another peel pouch;
- Placing a peel pouch inside of an instrument tray or container system (if not recommended by the manufacturer);
- Preparing textile packs that are too dense to sterilize in the cycle parameters chosen;
- Over loading the individual packaging or container system chosen (an over weight package).

Loading problems include:

- Stacking container systems (if not recommended by the manufacturer);
- Laying peel pouches flat or on top of each other instead of on edge;
- Improperly placing peel pouches on edge (plastic sides not facing all in one direction);
- Turning instrument trays on edge;
- Laying fabric packs or basins flat;
- Placing packages too close to each other impeding air removal and sterilant penetration around and through the load;
- Rigid containers systems loaded above wrapped or pouched items.

Malfunctioning equipment can also result in insufficient sterilization conditions inside of packaging as the result of:

- Incomplete air removal;
- Inadequate cycle temperature;

- Insufficient time at temperature;
- Poor steam quality and quantity.

As discussed above, small reductions in time at temperature can reduce the margin of safety with steam processing. Problems that limit air removal or steam penetration in individual packs may reduce the effective time at temperature. Type 5 Integrating Integrators that meet ISO 11140-1:2014 *Sterilization of healthcare products-Chemical Indicators-Part 1*: *General requirements* used inside each pack to monitor time, temperature and steam exposure conditions can provide the necessary sterilization assurance on a pack-to-pack basis.[7]

Load control is the process by which a load is monitored and released based on the result of a Biological Indicator (BI) in a process challenge device (PCD). A BI PCD should be used, preferably every day the sterilizer is used, for routine sterilizer efficacy testing. BI PCDs are also recommended for sterilizer qualification testing.[4,5] A BI PCD that includes a Type 5 Integrating Indicator should be used to monitor each implant load. The load should be quarantined until the results of the BI testing are available.[4,5] In non-implant loads, a PCD containing a Type 5 integrating indicator or Type 6 emulating indicator may be used to release the load.

Using a BI in every load (ELM) is considered best practice. When you monitor every load with a BI you provide the same level of care to each and every patient served by the facility. Every load monitoring allows only one load to be recalled, affecting fewer departments, and protecting the reputation of the department and the facility overall. It allows the CSD Manager to streamline workflow, simplify training and reduce the opportunity for human error which leads to consistent/standardized practice. Follow the process for every load and reduce the risk of failing to properly monitor an implant load.

Product Description

3M™ Attest™ Steam Chemical Integrators 1243A, 1243B and 1243RE are chemical indicators consisting of a paper wick and steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a green window marked ACCEPT or red window marked REJECT; the extent of migration depends on steam, time, and temperature. 3M™ Attest™ Steam Chemical Integrators are Type 5 (Category i5) Integrating Indicators as categorized by ISO 11140 1:2014.

This product comes with an extender strip affixed to one end of a 3M™ Attest™ Steam Chemical Integrator. The affixed 1243RE extender is a 17.8cm (7 in) long by 1.8cm (0.7 in) wide rigid strip. The affixed 1243RES extender is a 5.1cm (2 in) long by 1.8cm (0.7 in) wide rigid strip. The extender serves as a handle to retrieve processed integrators from inner packs.

Indications for Use

Outside the United States

Use 3M™ Attest™ Steam Chemical Integrators for pack control monitoring of all 121–135°C (250–275°F) steam sterilization cycles.

Inside the United States

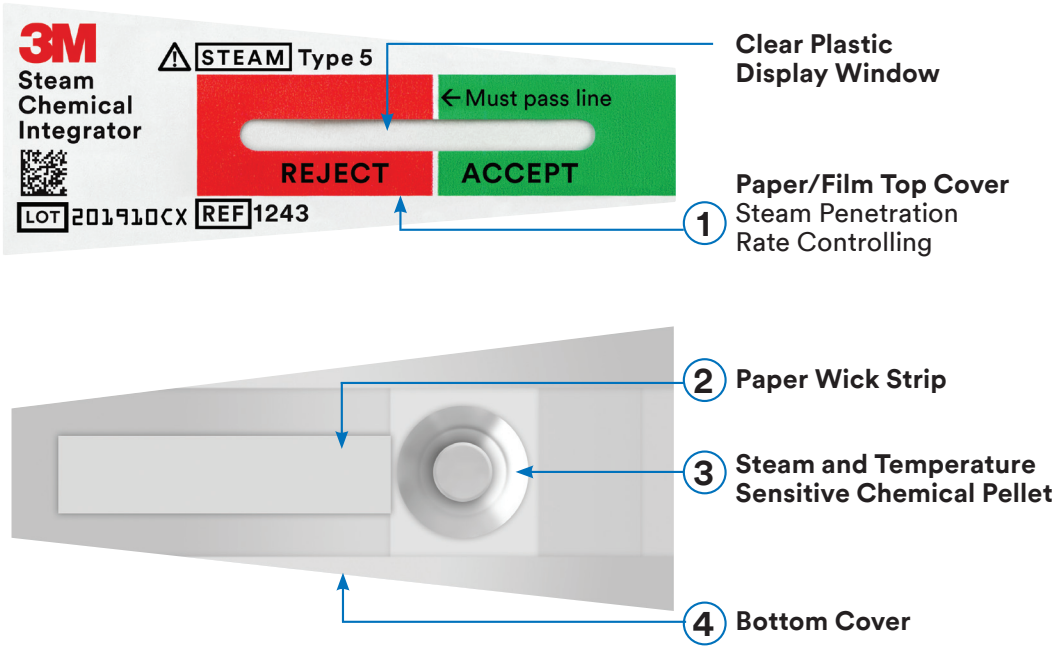
The 3M™ Attest™ Steam Chemical Integrators are designed to respond to all critical parameters over a specified range of steam sterilization cycles. The integrating indicator is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for sterilization cycles. Please see Instructions for Use for specific cycle indications for use in the U.S.

Contraindications

None.

Precautions

Do not use 3M™ Attest™ Steam Chemical Integrators to monitor dry heat, ethylene oxide, hydrogen peroxide, or other low temperature sterilization processes.



Technical Design

The 3M™ Attest™ Steam Chemical Integrator is made of four functional components. These components are arranged in a sandwich configuration held together with a pressure-sensitive adhesive: (See above)

1. **Steam penetration rate controlling paper/film top cover**
2. **Paper strip (for chemical wicking)**
3. **Steam and temperature sensitive chemical pellet**
4. **Aluminum foil bottom cover**

The base of the 3M™ Attest™ Steam Chemical Integrator is made of aluminum foil several mils thick which acts as a moisture barrier against steam penetration during sterilizing. A cavity embossed in the foil holds the temperature and steam sensitive chemical pellet. The pellet has a very high dry heat melting point to ensure 3M™ Attest™ Steam Chemical Integrators require the presence of steam in order to respond. However, it is designed to melt at lower temperatures when subjected to a steam environment. The top cover of the 3M™ Attest™ Steam Chemical Integrator is a paper/polymeric film which allows steam to penetrate at a certain rate. As steam penetrates the polymeric cover film, it lowers the melting point of the chemical causing the tablet to begin melting.

When melting occurs, the liquid chemical is absorbed by the paper wick and, as time elapses, moves along the scale. The more the chemical melts, the farther the color front advances towards the ACCEPT area of the display window. This is in part a function of the moving-front technology. The rate at which the chemical pellet melts is a function of the time, temperature, steam and the inherent design of the 3M™ Attest™ Steam Chemical Integrator. The combination of these factors provides a rate of melting at various temperatures which closely follows the spore death curve of *G. stearothermophilus* (proven to be the best challenge in a steam sterilization process) (see Figure 1).

Chemical Indicator Types

3M™ Attest™ Steam Chemical Integrators meet the requirements of ISO 11140-1:2014 for Type 5 Integrating Indicators. These indicators are designed to monitor all three of the critical variables of the steam sterilization process (time, temperature and steam) across full range of steam sterilization temperature use.

Third Party Testing

As part of our compliance process, 3M hired BSI, a leading global independent product testing services company, to confirm that 3M™ Attest™ Steam Chemical Integrators meet the Type 5 Integrating Indicator performance requirements of ISO 11140-1:2014. Through rigorous product testing, BSI confirmed these products meet the performance requirements of ISO 11140-1:2014. A copy of the BSI Kitemark™ Certification is available upon request from 3M.

Performance Characteristics

The 3M™ Attest™ Steam Chemical Integrator has been tested at various time and temperature intervals in saturated steam in a test vessel (called a resistometer) to determine compliance to the chemical indicator standards listed in the Chemical Indicator Types section above. To meet the Type 5 Integrating Indicator performance standards, the 3M™ Attest™ Steam Chemical Integrator must have a response that correlates to the performance of a BI at three temperatures (121°C/250°F, 135°C/275°F, and one or more equally spaced temperature points in the range of 121°C/250°F to 135°C/275°F, such as 128°C/263°F).[7] These responses are called Stated Values. Stated Values are "value or values of a critical process variable at which the indicator is designed to reach its endpoint as defined by the manufacturer."[7] In addition, the Stated Value at 121°C/250°F must be >16.5 minutes and the 135°C/275°F stated value must be >1.2 minutes.[7]

These are the most important Stated Values to ensure that chemical indicators labeled for use in 132°C/270°F do not change too quickly or inappropriately at lower and higher temperatures (to ensure the performance of the CI is consistent between all temperatures) and to ensure that all temperatures correlate to the performance of a BI. Furthermore, all of the ISO 11140-1:2014 Type 5 performance requirements must be met to ensure that the CI can detect improper sterilization conditions inside of each pack/container. Figure 1 shows three typical Stated Values for the 3M™ Attest™ Steam Chemical Integrators.

Instructions For Use

Placement and Processing

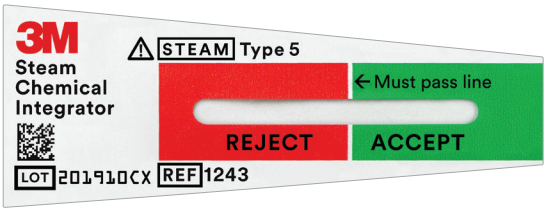
1. Carefully tear or use scissors at the tear notch at the top of the foil package to make the initial opening. Remove only the number of 3M™ Attest™ Steam Chemical Integrators needed. Reseal the package.
2. Place a 3M™ Attest™ Steam Chemical Integrator in each pack, peel pouch, container system or tray to be steam sterilized in the area determined to be the least accessible to steam penetration.
3. Process the load according to established procedures.

Note: Refer to the package insert for a complete set of instructions.

After processing, the dark color should have entered the ACCEPT window of the 3M™ Attest™ Steam Chemical Integrators 1243A, 1243B and 1243RE. If the dark color has not entered the ACCEPT window, this indicates a REJECT result which means that the items in the pack, peel pouch, container system, or tray were not exposed to sufficient steam sterilization conditions. These items should be returned for reprocessing.

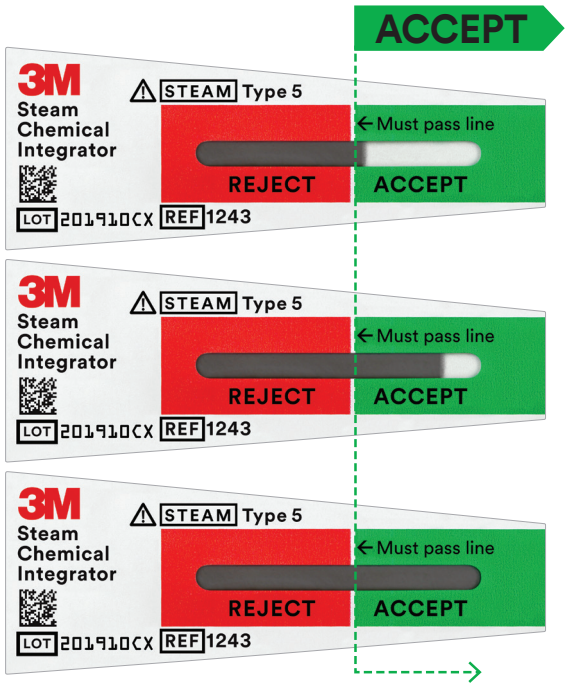
Interpretation of Results

Unprocessed



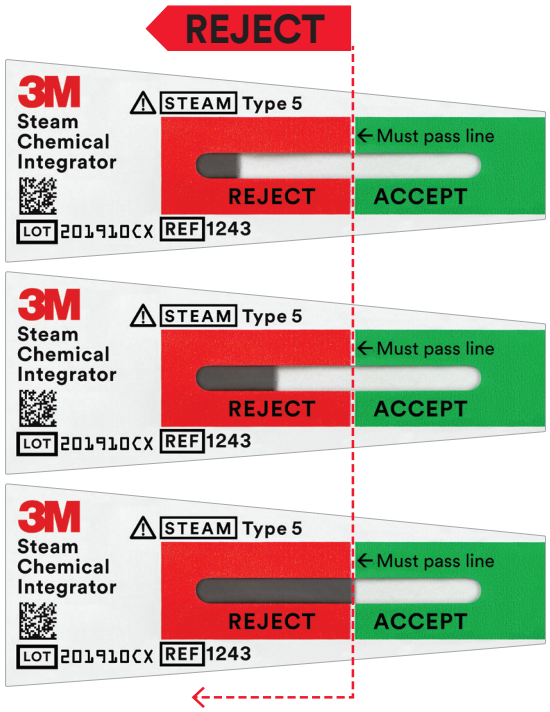
Processed — ACCEPT

If the color bar reaches or crosses into the ACCEPT window, it is a pass and the necessary conditions of time, temperature and steam have been met for sterilization.



Processed — REJECT

If the color bar is in the REJECT region or on the line, it is considered a fail. The pack should be reprocessed and the cause of sterilization failure should be investigated.



Safety

The design of the 3M™ Attest™ Steam Chemical Integrator prevents the indicating chemicals of the CI from coming in contact with sterilized materials or personnel handling the device. The chemical, as a pellet before processing or as a melted color front after processing, is contained in an envelope of impermeable top and bottom layers.

Storage and Shelf Life

- Best stored at normal room temperature conditions, 15–30°C (59–86°F) and 40–60% relative humidity. Store away from direct sunlight. Do not store near strong alkaline or acidic products such as cleaning/disinfecting agents.
- After use, the indicator will not change visually within 6 months when stored at above conditions.
- 3M™ Attest™ Steam Chemical Integrators contained in an unopened package have a shelf life as labeled from date of manufacture when stored at recommended conditions. The expiration date is printed on the package label and is also contained in the barcode on each device.

References

[1] Perkins, J.J., Principles and Methods of Sterilization In Health Sciences, ed 2, Springfield, IL, Charles C. Thomas, 1976.

[2] Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control, Technical Report No. 1 (Revised 2007), *PDA Journal of Pharmaceutical Science and Technology*, Supplement Vol. 61, No. S-1, 2007.

[3] International Standard. Sterilization of health care products Biological indicators — Part 7: Guidance for the selection, use and interpretation of results, ANSI/AAMI/ISO 11138-7:2019.

[4] Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79: 2017.

[5] The Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings, 2020.

[6] The Association of periOperative Registered Nurses (AORN) Recommended Practices for Selection and Use of Packaging Systems for Sterilization, 2020.

[7] International Standard. Sterilization of health care products-Chemical indicators-Part 1: General requirements, ISO 11140-1:2014.

3M Medical Solutions Division
3M Health Care
3M Center, Building 275-4E-01
St. Paul, MN 55144 USA

Phone **1-800-228-3957**
Web **3M.com/Medical**

Learn more on our website:
3M.com/Attest