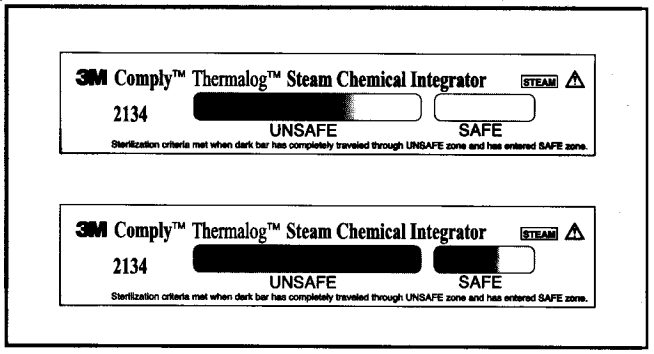
Technical Information Sheet

3M™ Comply™ Thermalog™ Steam Chemical Integrator

Dynamics of Steam Sterilization



Steam sterilization has been used throughout the twentieth century. Decades of research have shown that the integrity of a steam sterilization process is the function of three basic parameters: time, temperature and the presence of saturated steam. All three are critical 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 holding time of 60 minutes at 320°F (160°C), while steam sterilization at this temperature would take less than one minute.[1] Clearly, steam hastens 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] $t = F_o \times 10^{(250-T)/Z}$

t = time for 100% kill at temperature T
T = processing temperature
F_o = kill time for given organism 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)

Interpretation of this formula shows that the relationship of processing time (t) versus temperature (T) is 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. The accompanying graph shows the thermal death time at different temperatures for one million live spores of *Bacillus stearothermophilus*.[3] This curve can be expressed mathematically by the following formula:

$t = (11.8)10^{(250-T)/20.5}$

Where
F_o = 11.8 for *B. stearothermophilus*
Z = 20.5 for *B. stearothermophilus*

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

$t = (11.8)^{(250-T)/20.5}$
$t = (11.8)10^{(0.146)} = (11.8)(1.4)$
t = 16.5 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 16.5 minutes would be required to kill the one million live spores of *B. stearothermophilus.*

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 operator inadvertently set the processing temperature at 247°F (119°C) instead of 250°F (121°C). Or, if due to a minor malfunction of the sterilizer or a slight calibration error in the temperature monitoring system, a load was processed at 247°F or lower.

Because even small decreases in temperature during steam sterilization may significantly increase the time necessary for 100% kill, accurate means of monitoring internal sterilizer conditions are essential.

Pack Control

The dynamics of steam sterilization proves the need for monitoring of the sterilization process conditions. Load control is the process in which a load is monitored and released based on the result of a biological indicator (BI) in a test pack. Pack control monitoring, recommended by organizations such as AAMI and AORN, consists of monitoring individual packs based on readouts from chemical indicators from inside each pack.

As stated by AAMI and AORN, problems can occur with equipment malfunctions or in packaging and loading of packs into sterilizers. These problems can inhibit air removal and steam penetration. Examples of equipment malfunctions include a localized air leak due to a faulty door gasket or a poorly operating steam trap. Examples of packaging problems include stacking peel pouches and packs that are too heavy or dense.

As discussed above, small reductions in time or temperature can reduce the margin of safety with steam processing. Problems that limit air removal or steam penetration in individual packs will have the effect of reducing the effective temperature and/or time exposure. 3M™ Comply™ Thermalog™ Steam Chemical Integrators in controlled testing[4] have shown the ability to monitor/integrate time, temperature and steam exposure conditions, which are necessary to assure proper sterilization. On a pack-to-pack basis, chemical integrators are one of the many tools used to help provide sterilization assurance and identify potential problems in the sterilization process.

Product Description

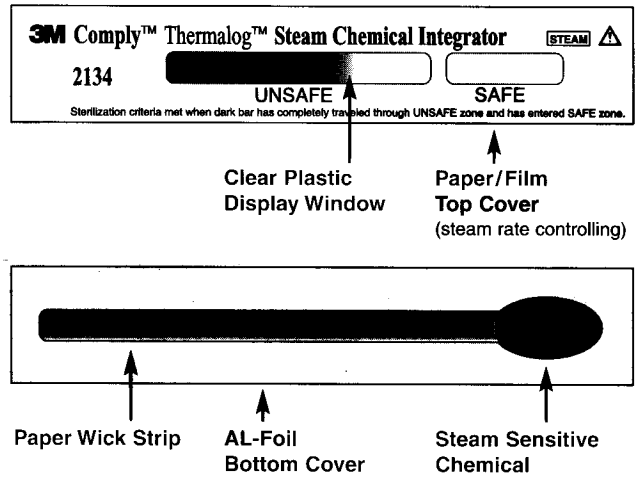
Indications For Use

The 3M™ Comply™ Thermalog™ 2134MM Steam Chemical Integrator is a single-use device that indicates whether materials within a pack have been exposed to the conditions necessary for sterilization. This device can be used for pack control monitoring of 245°F (118°C) to 280°F (138°C) gravity displacement and pre-vacuum steam sterilizers.

The easy-to-read Comply Thermalog steam chemical integrator features a color bar that advances into the "SAFE" window area or "UNSAFE" window area. A SAFE reading indicates that all the critical parameters of steam sterilization have been met. An UNSAFE reading indicates that sterilization conditions inside the pack were insufficient. If the bar does not reach the SAFE window, the pack should be reprocessed and the cause of the sterilization failure should be investigated.

For convenience, the 3M™ Comply™ Thermalog™ 2163MM Steam Chemical Integrator consists of an extender strip affixed to one end of a Comply Thermalog 2134MM steam chemical integrator. The extender is used as a handle for retrieving the processed integrator from the center of packs.

Comply Thermalog 2134MM and 2163MM steam chemical integrators should not be used to monitor dry heat, ethylene oxide (EO) or other low temperature sterilization processes.



Technical Design

The Comply Thermalog 2134MM steam chemical integrator is made of four functional components. These components are arranged in a sandwich configuration held together with a temperature-resistant, pressure-sensitive adhesive: (See above)

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

The base of the Comply Thermalog 2134MM integrator is made of aluminum foil 3 mils thick which acts as a moisture barrier against steam during sterilizing. A cavity embossed in the foil holds the temperature and steam-sensitive chemical. The chemical has a dry heat melting point of 285°F (139°C). However, it is designed to melt at lower temperatures when subjected to a steam environment. The moisture of steam depresses the melting point down to the actual sterilization temperature. If the melting point of the chemical was lower than the desired sterilization temperature, steam penetration would not be required and the device would be capable of reaching the SAFE area without the necessary presence of steam.

The top cover of the Comply Thermalog 2134MM 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 it to begin melting.

When melt occurs, the liquid chemical is soaked up 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 SAFE area of the display window. The rate of chemical tablet melt produced is a function of both the moisture-vapor transmission rate of the cover film and the melting point depression of the chemical tablet. The combination of these two factors provides a rate of melt at various temperatures which closely follows the spore death curve of *B. stearothermophilus* (proven to be the best challenge in a steam sterilization process).

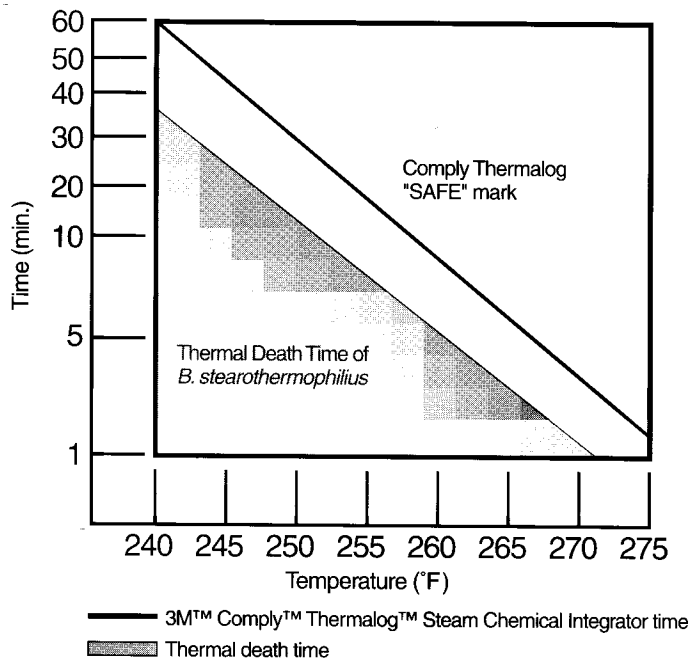
The Comply Thermalog 2163MM steam chemical integrator includes a 7-1/2 in. (19 cm) long by 3/8 in. (1 cm) wide rigid, paperboard strip affixed to the backside of the integrator device. The extender serves as a handle to retrieve processed integrators from inner packs.

Performance Characteristics

The Comply Thermalog integrator was tested at various time and temperature intervals in saturated steam, in order to estimate the time required at each temperature for the integrator to produce a SAFE reading. Four temperature points between 245°F and 275°F were tested for at least four separate time periods.[4] This testing resulted in the following mean (average) times to produce a SAFE reading for each of the four temperatures tested:

Temperature (°F)	Time (minutes)
245°	35.0
250°	18.5
260°	5.5
270°	1.9

A plot of the performance equation of the Comply Thermalog steam chemical integrator in comparison with the performance of *B. stearothermophilus* spores is shown in the graph below. The graph compares the Comply Thermalog integrator
with the performance of biological indicator spore strips (*B. stearothermophilus*) in a steam BIER vessel. The graph represents sterilization cycle time only, exclusive of come-up or -down time. The performance of the Comply Thermalog integrator in the BIER vessel parallels the response of the biological indicator spore strip within the normal sterilization range.



Chemical Indicator Classification

CEN Standard

Comply Thermalog 2134MM steam chemical integrator meets the general requirements of EN 867-1:1997 European Standard for Class D: 'Multi-variable' indicators. This indicator is designed to monitor all three of the critical variables in the steam sterilization process.

Instructions For Use

Placement and Processing

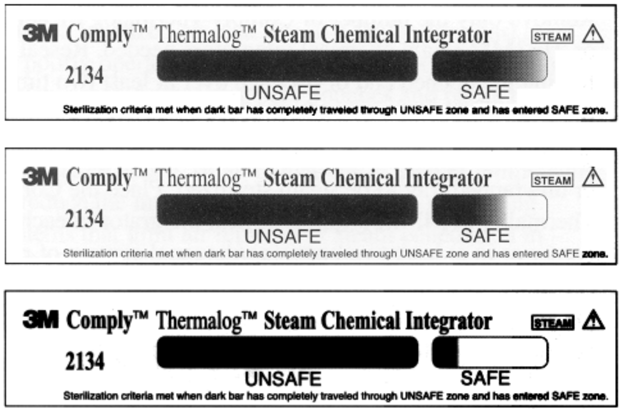
1. To preserve as much package as possible for resealing, cut along marked line at the top of the foil package to open. Remove only the number of Comply Thermalog 2134MM or 2163MM steam chemical integrators needed. Reseal by folding the opened end of package over at least two times.
2. Place a Comply Thermalog 2134MM or 2163MM steam chemical integrator in the center of each pack, peel pouch or unwrapped tray to be steam sterilized. Place the Comply Thermalog 2134MM steam chemical integrator in each corner or in at least two opposing/diagonal corners of rigid containers or in the area determined by product testing to be the greatest challenge. If using an integrator with extender, position the unattached end of the extender so that it extends slightly beyond the inner contents of the pack.
3. Process load according to established procedures. If using an integrator with extender, after processing, grasp the extender between the thumb and forefinger to remove integrator from the inner pack.

How to Read the 3M™ Comply™ Thermalog™ Steam Chemical Integrator

Interpretation of Results

1. After processing, the dark color should have entered the SAFE window of the Comply Thermalog 2134MM steam chemical integrator. If the dark color has not entered the SAFE window, an UNSAFE result is indicated. This means the items were not exposed to sufficient steam sterilization conditions. These items should be returned for reprocessing.

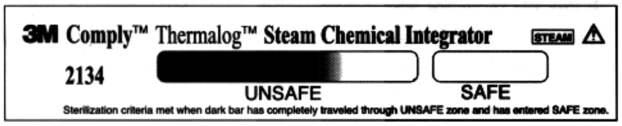
SAFE



The color bar has reached the SAFE window in all three samples shown above, indicating that the necessary conditions for sterilization have been met.

2. If several packs, peel pouches or trays in a load contain integrators with UNSAFE results, review the biological indicator results. Check all areas of the process for cause of failure.

UNSAFE



The color bar is in the UNSAFE *window, indicating that the necessary conditions for sterilization have not been met.*

Safety

The design of the Comply Thermalog 2134MM steam chemical integrator prevents the indicating chemicals from coming in contact with sterilized materials or handling personnel. The chemical, as a tablet before processing or a melted color front after processing, is contained in an envelope of impermeable top and bottom layers.

Storage and Shelf Life

Unopened and resealed packages containing Comply Thermalog 2134MM steam chemical integrators should be stored in a dry (<50% RH) condition at room temperature [59–86°F (15–30°C)]. Comply Thermalog 2134MM steam chemical integrators contained in an unopened package have a five-year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the package label.

References

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

[2] Akers, M., Attia, I., Avis, K., "Understanding and Utilizing F_o Values." *Pharmaceutical Technology,* 1:31–35, May 1978.

[3] Whitborne, J., Ferris, B., Morien, L., "Dynamics of Steam Sterilization, Developments in Industrial Microbiology," Arlington, VA, *Society for Industrial Microbiology,* 1976, p 361.

[4] BIER vessel data on file at 3M.

3M

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