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Health Care Logistics® INC.

# Technical Bulletin

# Monitormark™ Product Exposure Indicators

MonitorMark is a trademark of 3M

MonitorMark™ Tags pinpoint time as well as temperature. They are easy to handle. They provide quick analysis in a myriad of situations requiring time/temperature exposure monitoring.

**GENERAL DESCRIPTION:**

Each tag consists of an indicator strip containing a reservoir pad with a colored organic compound that reacts to a specific melting point. A film barrier strip separates these two elements. Removal of the filmstrip activates the tag (See page 4). Placed directly on secondary shipper boxes of temperature-sensitive products during shipment and storage, the indicators provide information to assist in estimating time and temperature exposure.

Monitor Mark tags provide the user information to help judge the quality of perishable products.

1. The appearance of a blue color in a tag's window indicates that a critical temperature has been exceeded.

2. The extent of the movement of the blue color through the tag's five windows provides a measure of the accumulated time spent above the critical temperature.

No color change means no problem. If the tag remains below the threshold temperature the color indicator does not move, and it's immediately apparent that the product has been maintained at recommended temperatures.

**UTILIZATION:**

To monitor the exposure of a product above a certain critical temperature, choose a Monitor Mark tag having a threshold temperature closest to that critical temperature. Apply the tag to the product to be monitored. The tag needs to be pre-conditioned below its threshold temperature. Activate the tag. Then as long as the product remains below this temperature, no change in the tag will take place. When the threshold temperature of the tag is exceeded, a blue color appears in the window farthest to the left; it proceeds to the right as exposure continues. The extent of color movement is called "runout".

The location of blue color in the tag's windows is a function of time as well as temperature. A short exposure at a relatively high temperature will produce coloration comparable to a longer exposure at a lower temperature. The tag is also able to record cumulative time spent above the threshold level; if the temperature falls below the set point the color indicator stops, then resumes again with temperature increase.

If the temperature remains above the threshold temperature, the blue color will continue to move toward the end of the tag. If the temperature drops below the threshold temperature, the position of the blue color will freeze in place, only to resume its forward movement if the temperature again goes above the threshold temperature. Also the rate, at which the color moves, increases as the temperature goes up (much as the rate of deterioration of a perishable product increases as temperature goes up).

Each type of tag has associated with it a response card to allow a determination of the time/temperature conditions a tag, and the product it monitors, has been exposed to. This card shows how many hours are required for the blue color to move to any particular position in one of the tag windows at a given constant temperature. Two time/temperature scales are shown on the card, each run at a different constant temperature. If the product can only tolerate a limited exposure to elevated temperatures, the readout on these tags will help a recipient make a confident decision on whether to accept or refuse a shipment. The response card should be provided to the recipient so that the proper readings can be obtained upon receipt of product.
The indicators monitor temperature exposure, not product quality. Their purpose is to signal when product quality should be checked. Some typical applications include monitoring of drugs, vaccines, medical diagnostic kits, blood substances and ophthalmic solutions.

MonitorMark Time Temperature Tags are available from HCL as standard products at three threshold temperatures with cumulative run-out times of 2 or 7 days

**STORAGE:**
Store Monitor Mark time/temperature indicators in a controlled environment at 22˚C (72˚F) at 20 - 60% relative humidity. Keep away from heating vents, hot pipes or direct sun. If stored at these conditions, shelf life is two years from date of manufacture.

Indicators stored in a freezer should be removed and allowed to warm for a short time at ambient room temperature prior to attachment to allow for adequate adhesion on some surfaces. All mounting surfaces should be pretested to insure desired adhesion.

**PRE-USE CONDITIONING:**

Use the temperatures listed in the table below for proper conditioning of the Tags. This will insure solidification of the indicator's response chemical and accurate time/temperature runout during usage. Tags should be pre-conditioned for at least two hours minimum before use. Longer time and/or lower temperatures are desirable and will not harm the functionality of the indicator.

**INTERPRETATION:**

Appearance of blue color in the tag's window indicates that a critical temperature has been exceeded.

Extent of color movement through the tag windows provides a measure of the accumulated time spent above the critical (threshold) temperature. A short exposure at a relatively high temperature will produce coloration comparable to longer exposure at a lower temperature.

The included response card is used to interpret the time/temperature relationship for each tag. The card contains complete instructions for users to analyze any evidence of over-temperature exposure and its effect on the tagged product. Read time exposure according to the color advancement card included in the product package.

When the recipient's knowledge concerning the shelf life of the product associated with this tag is factored in, an accurate decision can be made on product usability.

For a more detailed profile of product exposure conditions, two or more tags can be combined with different threshold temperatures. This process is known as bracketing.

**LIMITATION OF LIABILITY:**

All physical properties, statements and recommendations are either based on tests 3M believes to be reliable or their experience, but they are not guaranteed. The user is responsible for determining whether this 3M product is fit for a particular purpose and is suitable for user's method of application.

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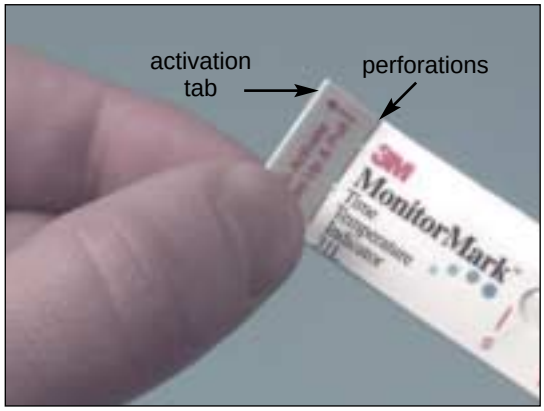
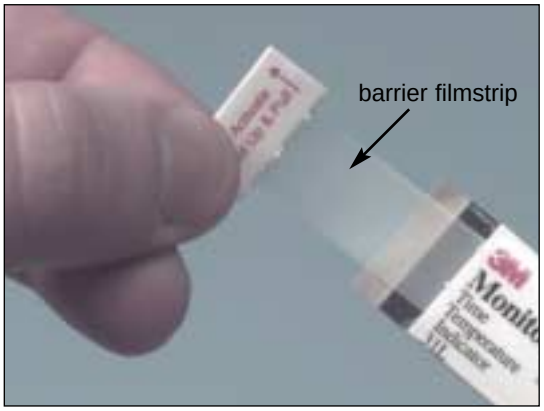
| HCL No. | 3M Number | Description | Cum. Exposure Runout Time | Pre-use Conditioning Table |
|---|---|---|---|---|
| **8201-01** | **5I** | 5˚C (41˚F) and above | 48 hours | ≤ -1˚C (25˚F) or Freezer |
| **8205-01** | **10I** | 10˚C (50˚F) and above | 48 hours | ≤ + 5˚C (41˚F) or Freezer |
| **8207-01** | **10L** | 10˚C (50˚F) and above | 1 week | ≤ + 5˚C (41˚F) or Freezer |
| **8208-01** | **TTI - 9860H** | 31˚C (88˚F) and above | 1 week | ≤ 26˚C (79˚F) or Freezer |

# Instructions for Activating and Applying Indicators




**To activate indicators for use:**

1. Fold up on the perforated activation tab located on the left side of the indicator.




2. Pull the activation tab out and the attached barrier filmstrip will come with it. The indicator is now ready to monitor temperatures.

**Attachment instructions:** Peel the tan backing from the indicator until the white adhesive area is exposed. Press the white adhesive onto a clean, dry area by applying pressure to the indicator.

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