

3M MonitorMark™

Time Temperature Indicators

Providing a visual history of time temperature exposure.

Whether it's a vaccine, drug, blood substance or ophthalmic solution, you cannot afford to have your product's quality compromised at any stage of the process. However, unknown and unpredictable temperature conditions can hinder your ability to ensure that your customers are receiving products of the highest possible quality.



3M™ MonitorMark™ Time Temperature Indicators add an important temperature exposure measure that extends beyond your plant to your customers' delivery dock.

MonitorMark™ Time Temperature Indicators not only signal when a threshold temperature has been exceeded, but provide an easy-to-read visual signal to estimate the minimum amount of time a product has spent above the threshold temperature.

MonitorMark™ indicators feature a high contrast indicator that turns blue as a result of exposure to rising temperatures. The indicator is irreversible, providing a permanent record of temperature exposure even after temperatures return to acceptable levels.

Placed inside secondary shipper boxes of temperature-sensitive products during shipment and storage, the indicators provide information to assist in estimating time and temperature exposure.

MonitorMark™	Threshold Temperature °C/°F (starts to move) Recording time ¹	Typical Temperature °C/°F to Stop Moving	Conditioning Temperature °C/°F (2 hours minimum)
9860A	-15°C/5°F 48 hours	-20°C/5°F	-25°C/-13°F or below
9860B	5°C/41°F 48 hours	0°C/32°F	-4°C/25°F or below
9860C	10°C/50°F 48 hours	7°C/44.6°F	5°C/41°F or below
9860D	10°C/50°F 1 week	7°C/44.6°F	5°C/41°F or below
9860E	26°C/79°F 48 hours	24°C/75°F	21°C/70°F or below
9860H	31°C/88°F 1 week	29°C/84°F	26°C/79°F or below
9861A	TTI 10°C/50°F 2 weeks End Dot 34°C/93°F	TTI 7°C/44.6°F End Dot N/A	5°C/41°F or below
9864C	TTI 10°C/50°F 24 hours End Dot 17°C/62.6°F	TTI 7°C/44.6°F End Dot N/A	5°C/41°F or below

¹ Maximum time it takes the blue to run the entire length of tag at 2°C above threshold temperature.

Where and How to Use

MonitorMark™ Time Temperature Indicators can be used to monitor any product exhibiting time temperature abuse sensitivity. They are used as part of the secondary package to monitor storage and transportation conditions. These simple to use and easy to read indicators signal when product quality should be checked. The MonitorMark™ Time Temperature Indicators monitor exposure not product quality. Some typical applications include monitoring of drugs and vaccines, medical diagnostic kits, blood substances and ophthalmic solutions.

Pre-Use Conditioning

To prevent premature response, MonitorMark™ Time Temperature Indicators (including dual temperature indicators) must be conditioned prior to removing the activation strip and activating the indicators. This insures that the response chemical is solid and not liquid prior to removing the activation strip. Condition indicators for a minimum of two hours in a suitable refrigerator, freezer or chamber at or below the temperature shown in the product table.

Once conditioned and ready for use, the indicators can be maintained at any temperature below their critical temperature.

Note: It is the indicator that must be cooled to the conditioning temperature listed in the chart not the product that is going to be monitored. The product need only be maintained below its critical temperature.

Correct Surface Temperature During Indicator Activation

At the moment the time temperature indicator is activated by pulling the activation strip. The surface to which it is attached (carton, instruction card, product itself, etc.) must be at a temperature below the threshold temperature of the indicator. Otherwise, the heat from the carton or card could be enough to cause a premature response in the indicator.

Activation

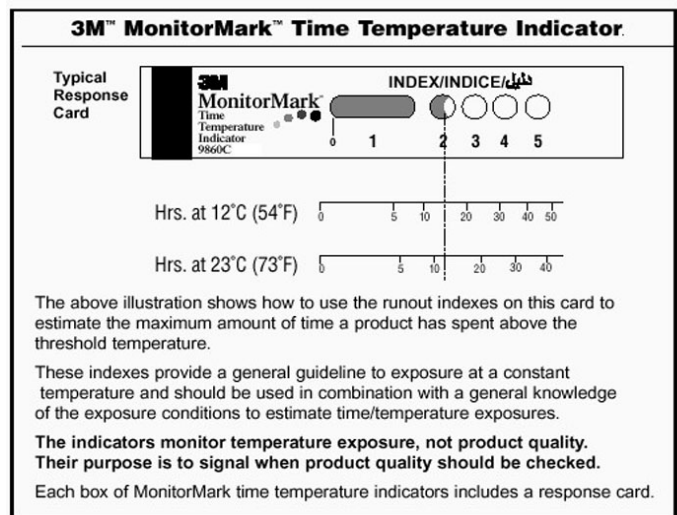
After proper pre-use conditioning, the monitoring process is started by simply pulling the side tab up and removing the activation strip. This allows contact between the reservoir pad and the end of the porous wick indicator track. At this point the indicator track (visible under the viewing windows) is a plain white color. Upon exposure to temperatures exceeding the critical response temperature, the chemical in the reservoir melts and begins to migrate along the track. Thus, blue coloring first appears at the left edge of the first viewing window and gradually moves left to right to the end of the track. The rate of the blue color movement is dependent on the temperature.

Runout Interpretation

The appearance of any blue color in the indicator's first window signals the indicator's pre-set threshold temperature has been exceeded.

The extent of color movement ("runout") through the indicator's windows provides an estimate of the minimum amount of time spent above the threshold temperature. A short exposure at a relatively high temperature will produce coloration comparable to a longer exposure at a lower temperature.

Response cards are used to interpret the time temperature relation for each indicator. The runout distance versus time relationship for two temperatures is provided. Below is an example of a typical response card.



Performance

MonitorMark™ time temperature indicators will show initial color in 24 hours or less when exposed to the stated threshold temperature, $\pm 1^\circ\text{C}$. When exposed to a constant temperature 2°C above the threshold temperature for a time period equal to the state cumulative runout time, the runout distance will be within $\pm 9\%$ of the target distance.

Note: Indicators are designed to run (blue color movement) when the temperature exceeds the threshold. After this occurs, the indicators will continue to run until the temperature falls below the stopping temperature listed in the product table.

Product Construction

The 3M™ MonitorMark™ Time Temperature Indicator is a rectangular flat laminate containing layers of paper, film, adhesive and other components. The heart of the indicator is a porous wick indicator track strip, one end of which is positioned over a reservoir pad containing a blue-dyed specialty chemical having a desired melt point. Before activation, a removable activation strip separates the indicator track from the reservoir. A paperboard layer over these components contains viewing windows and is topped with a clear protective film over layer. A pressure-sensitive adhesive on the underside of the indicator allows convenient attachment to most clean, dry surfaces.

Size: 3-3/4" X 3/4" X 3/32" thick (approx.)
(95 mm X 19 mm X 2 mm, approx.)

Packed: 100 per box or 5 boxes (500 units) per case.

Storage

MonitorMark™ Time Temperature Indicator can be stored at 22°C (72°F) and 20-60% relative humidity. However, for ease of use you can store them below the stopping temperature (but above -40°C). Keep away from heat, such as, heating vents, hot pipes or direct sun.

Shelf Life

If stored at approximately 22°C (72°F) and 20-60% relative humidity, shelf life is two years from date of manufacture. Date of manufacture can be determined from the Julian date lot number. The first digit of the lot is the last digit of production year and the following three digits is the number of days from January 1st.

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