

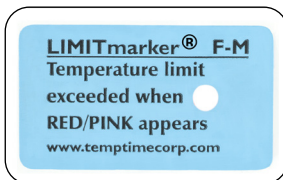


LIMITmarker® F

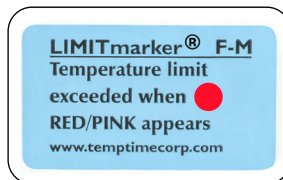
Time Delay Heat Threshold Indicator

- Identifies when a potentially damaging heat excursion has been experienced for a short period of time.
- Easy-to-read, irreversible visual color change.
- Used to identify and prevent the administration or use of products that can be damaged or lose strength after a high heat excursion.

LIMITmarker F, manufactured by Temptime, is a single-use indicator that provides an easy-to-read, irreversible visual color change when there has been exposure to a temperature above the threshold limit for a short period of time. LIMITmarker F technology is based on the precise melting of heat-fusible materials at specified temperatures. The easy-to-read color change from white to red/pink is a visual signal when there has been a heat excursion above the predetermined temperature profile. LIMITmarker can be affixed to an individual unit to monitor the product from manufacture to use, or later in the cold chain to monitor the product for a portion of its distribution. Many medical products can be damaged and lose strength when exposed to temperatures above a certain threshold. Such excursions can go unnoticed during shipping and storage. Leading medical product manufacturers and distributors use LIMITmarker F.



OK



OVERHEATED

Features

- Irreversible
- Easy to understand
- Single-use
- Time delay heat excursion
- No device activation required
- Nontoxic materials

Benefits

- Identify and avoid administration of heat exposed products
- Extend quality management system from manufacturing to ultimate use
- Strengthen conformance to International Code on Harmonization (ICH) Q9 and Q10
- Reduce unnecessary waste by limiting the destruction of products incorrectly suspected of heat damage
- Environmentally friendly

LIMITmarker® F

Performance and Use

Sensor Specifications

Response Temperatures: 9°C / 7.5°C / 25°C / 31°C

Accuracy: ±1°C

Response Time: Within 2 hours

Storage Temperature: Frozen: ≤ -6°C

Shelf Life: 4 years from date of manufacturing

Usage: Single use

Temperature Monitoring: Continual

Device Size: 22mm x 34.9mm

Additional Features: Adhesive backing

Quality System

- Temptime's quality management system is consistent with FDA Quality System Requirement (QSR) 21 CFR 820 (GMP for medical devices)
- ISO 9001
- ISO 13485



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