

Since 1996, more than **six billion** temperature indicators manufactured by Temptime have been affixed to temperature sensitive biologics shipped around the world

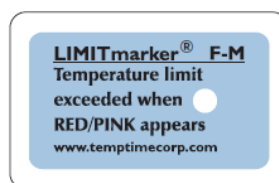


Temperature Intelligence™

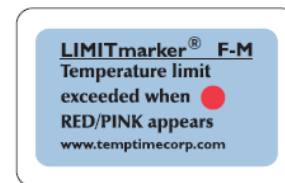
LIMITmarker® F

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.



OK



OVERHEATED

The LIMITmarker F 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. The 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 the LIMITmarker F.

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

Temperature Intelligence™

LIMITmarker[®] F

Performance and Use

- | | | | | |
|---------------------------|------------------------------------|--------|------|------|
| • Response Temperatures: | 9°C | 17.5°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: | 22.2mm 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



LIMITmarker is a registered trademark of Temptime Corporation.
COMZ LIMITmarker Product Sheet

Rev. 2