



LIMITmarker[®] I-K, I-C and I-P

Quick Response High Heat Threshold Indicators

- Identifies when a potentially damaging high heat excursion temperature has been experienced
- 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 I-K, I-C and I-P, manufactured by Temptime, are single-use indicators that provide an easy-to-read, irreversible visual color change when there has been exposure to a temperature above the threshold limit. LIMITmarker technology is based on the precise melting of heat-fusible materials at specified temperatures. The easy-to-read color change from grey to black is a visual signal when there has been a heat excursion above the predetermined temperature profile. They 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 I Threshold Indicators.



OK



OVERHEATED

Features

- Irreversible
- Adhesive backing
- Single-use
- Quick response time
- 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 I Thresholds

Performance and Use

Specifications

Response Temperature: I-K: 40°C; I-P: 45°C I-C: 50°C;

Accuracy: +/-1°C

Response Time: Quick (up to 15 minutes)

Storage Temperature: +20°C to +25°C or below

Shelf Life: 4 to 7 years from date of manufacturing

Usage: Single Use

Temperature Monitoring: Continual

Device Size: 10.5mm circle

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

Tap into the future of temperature monitoring at www.zebra.com/temppmonitoring



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