

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® I

Immediate Response High Heat Threshold Indicator

- 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.



OK



OVERHEATED

The LIMITmarker I 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. 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 the LIMITmarker I.

Features

- Irreversible
- Adhesive backing
- Single-use
- Immediate 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

Performance and Use

- Response Temperatures: 40°C 44°C 50°C
- Accuracy: ±1°C
- Response Time: Immediate (within 15 seconds)
- Storage Temperature: Frozen or Refrigerated: < +24°C
- Shelf Life: 6 years from date of manufacturing
- Usage: Single use
- Temperature Monitoring: Continual
- Device Size: 8mm 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

