

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

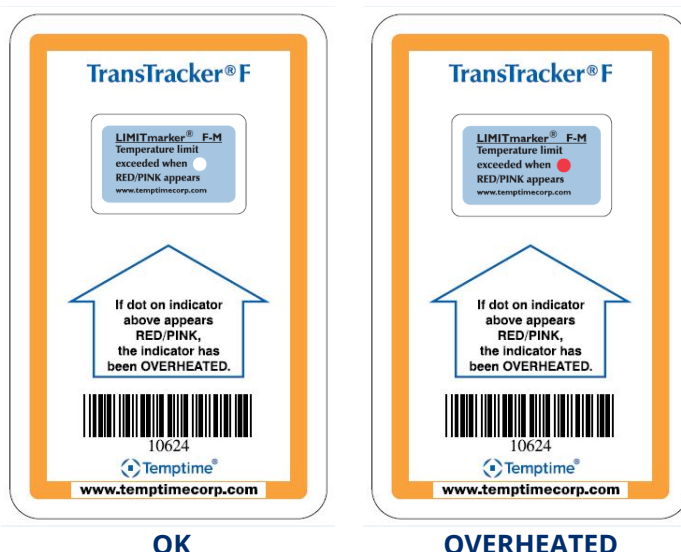


Temperature Intelligence™

# TransTracker® 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.



The TransTracker F card has a single-use LIMITmarker F indicator applied to it 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 TransTracker F card is placed inside multiple unit secondary packages or shipping boxes to monitor heat excursion during transportation. 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 TransTracker 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

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# TransTracker<sup>®</sup> 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:            | 54mm x 86mm                         |
| • Additional Features:    | Card design customization           |

## 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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COMZ TrTr F Product Sheet

Rev. 3