

**FACT SHEET**

TRANSTRACKER® CD FREEZE AND QUICK HEAT



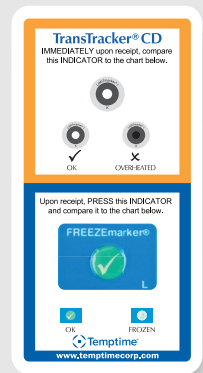
**ZEBRA**  
CAPTURE  
YOUR EDGE

# TransTracker® CD

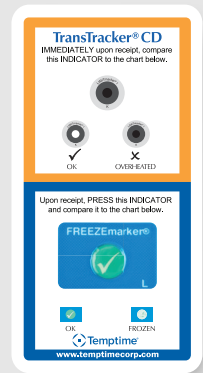
## Dual Freeze and Quick Response Heat Monitoring

- Identifies when a potentially damaging heat excursion or freeze event 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 or freeze event

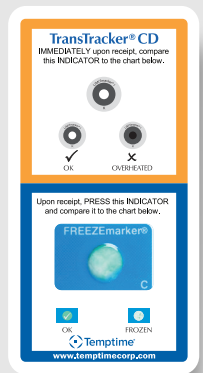
The TransTracker CD card has a single-use LIMITmarker I-K indicator and a FREEZEmarker indicator applied to it that provide an easy-to-read, irreversible visual color change when there has been exposure to a temperature above the threshold limit or to a freezing temperature for a short period of time. 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. When exposed to temperatures at or below a specified freeze temperature, the green circle will change to white opaque/cloudy. The TransTracker CD card is placed inside multiple unit secondary packages or shipping boxes to monitor temperature events during transportation. Many medical products can be damaged and lose strength when exposed to temperatures above a certain threshold or become frozen. Such excursions can go unnoticed during shipping and storage. Leading medical product manufacturers and distributors use the TransTracker CD.



**OK**



**OVERHEATED**



**FROZEN**

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### Features

- Irreversible
- Easy to understand
- Single use
- Quick heat excursion response
- Multiple temperature ranges
- No device activation required
- Nontoxic materials

### Benefits

- Identify and avoid administration of heat or freeze 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 or freeze damage
- Environmentally friendly

## TransTracker® CD

### Performance and Use

#### Response Temperatures:

Heat: 40°C

Freeze: 0°C / -1°C / -6°C (±2°C)

**Accuracy:** ±1°C

#### Response Time:

Heat: Quick (within 15 minutes)

Freeze: Within 30 minutes

**Storage Temperature:** Refrigerated temperature (2°C to 8°C)

**Shelf Life:** 2 to 4 years, determined by category

**Usage:** Single Use

**Temperature Monitoring:** Continual

**Device Size:** 56mm x 108mm

**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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