TransTracker® D

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.

The TransTracker D card has a single-use LIMITmarker I 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. LIMITmarker I 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. The TransTracker D 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 D.

Features
- Irreversible
- Easy to understand
- 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

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® D

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: 54mm x 86mm
- Additional Features: Card design customization

Quality System

- Temptime’s quality management system is consistent with FDA Quality System Requirements (QSR) 21 CFR 820 (GMP for medical devices).
- ISO 9001
- ISO 13485

LIMITmarker® I is manufactured by NiGK Corporation (Japan) and distributed in North & South America, Europe and India by TEMPTIME Corporation.
TransTracker is a registered trademark of Temptime Corporation.
COMZ TrTr D Product Sheet

Rev. 2