

The Cold Chain Information System

The **Cold Chain** Information System Temp<mark>Via</mark>Net TempTracer TempTracer enter Center PC or handheld terminal PC or handheld terminal Central Web Site Shipment Ar Statistics **Dispatching Site Receiving Site** onfiguration & Launch hipping Information ultiple or Single Usage ynchronization with TVI Reports . **Monitoring Throughout The Supply Chain**

System Overview

Pharmaceutical companies are generally required to monitor their temperature sensitive and valuable products during transportation and in storage. Retrieving and managing shipping information, including temperature data, as well as utilizing the information to make strategic business decisions are complex challenges.

The Cold Chain Information System (CCIS) is a comprehensive monitoring system developed to meet these challenges. The CCIS offers companies a competitive edge by controlling quality, meeting regulatory requirements, streamlining processes, and improving customer satisfaction.

The Cold Chain Information System is offered in three versions: standard, professional and enterprise, targeting both small businesses and large corporations.

The Cold Chain Information System

The CCIS offers a flexible software suite that can be combined and tailored to each customer's specific needs and requirements. Users can select to utilize single or multiple use sensors; work with a client based PC solution or a web-enabled solution. TSS offers three versions:

- The CCIS Standard Edition: client based PC solution
- The CCIS Professional Edition: PC solution in combination with basic web capabilities
- The CCIS Enterprise Edition: PC solution with full web functionalities

The CCIS main components are TempViaNet®, TempTracer Center and TempTracer®.

TempViaNet®

TempViaNet[®] (TVN) brings temperature monitoring to a new dimension, offering a unique Cold Chain Management tool. Independent of location and time, the TVN provides instant access to detailed shipment information, temperature history, statistics and trends. TVN empowers various stake holders within a company with an outstanding tool to ensure quality, compliance with regulatory requirements and to improve supply chain processes.

TVN is offered in two versions. The CCIS Professional Edition covers the basic functions, while the CCIS Enterprise Edition comprises the full advanced set of features.

CCIS Enterprise features

- Statistics and search
- Shipment analysis
- Status and trend analysis
- · Advanced and detailed report functions
- · Instant access 24/7 from anywhere in the world
- · Personalized data and report formats
- Purchase order capabilities
- Audit trail



TempTracer Center & TempTracer®

The TempTracer Center (TTC) is the most advanced client-based software for temperature monitoring, included in all three versions of CCIS. At product dispatching sites the TTC allows the user to configure and add optional shipping information to the TempTracer[®] data loggers. At product receiving sites the TTC is used to stop and download data from the data loggers. The application generates comprehensive temperature reports. All data can be sent to the central web application, TempViaNet[®]. The certified and calibrated TempTracer[®] data loggers are offered in both multiple and single versions.

TTC features

- Event based in-transit information
- Personalized temperature formats
 and print report processes
- Configuration of shipping information, alarm levels and sample rates
- · Launch, stop and download management
- Unique traceability management
- Local data storage
- · Comprehensive report capabilities
- Code 21 CFR Part 11 compliant







TempTracer® Specification

TempTracer® Specification	
Monitor type	Ambient temperature data logger
Operating range	-40° C to + 85° C
Temperature accuracy	± 0.5° C between -10° C to + 65° C
Memory capacity	4096 data points
Resolution	0.0625° C (1/16th of a degree)
Programmable temperature alarms	Total of 10 individual configurable high/low alarms with either single or cumulative events
Programmable sampling rate	1 minute to 255 minutes
Start-up delay	Clock controlled or time until start feature
Water resistance	1 meter under water for 30 days
Weight	Approximately 8 gram
Measurement	Height 86 mm, width 65 mm, thickness 6 mm
Housing	Stainless steel, highly resistant to dust, moisture, shock
Traceability	Guaranteed unique 64-bit registration number that allows for absolute traceability

Accessories

Verifier



Allows the user to stop a mission and check for temperature excursions.

T-connector



Interface reader between the TempTracer[®] data logger and the TTC software.

T-extender



Extension cord to be used with the T-connector for downloading a TempTracer[®] placed in a closed environment.

CCIS quality assurance

The validated Cold Chain Information System is a proven system already in use by leading pharmaceutical companies all over the world. CCIS complies with FDA's Federal Code 21 CFR Part 11 and is developed within the frames of GAMP4.

Security features

- Secured access control
- · Access rights management
- · Automatic audit logging
- · Log data filing system
- Secured data transmission



Supplementary products from TSS

TSS is a leader in cold chain management, providing a wide range of products. The product portfolio contains, in addition to the CCIS, CoolKeeper refrigerants and ProBox shipping containers. Since the establishment in 1992, TSS has provided the market with products and services for the supply chain of pharmaceuticals and perishables. TSS has the know-how, track record and proven technology required to deploy complete and successful solutions for cold chain management. Today our products are used by some of the largest pharmaceutical companies in the world.