

- Read 2-D and 1-D barcodes, including GS1 and securPharm
- Verify correct ID code and printed text, including compliance with the GS1 data standard
- Assess Data Matrix code quality at runtime to detect print degradation
- Validate In-Sight Track & Trace integration with available GAMP 5 documentation



Ready for Serialization

The In-Sight® Track & Trace identification and data verification solution for healthcare serialization addresses the requirements for pharmaceutical and medical device manufacturers to achieve unit-level and bundle product traceability. In-Sight Track & Trace software works with multiple networked In-Sight vision systems to decode human-readable text along with 2-D and 1-D barcodes.

The smart camera approach to traceability is less expensive to install, less complex to validate and less costly to maintain than previous options. Because it can be combined with a variety of third-party products, you have the flexibility to customize and scale serialization solutions to best suit your budget and needs.

The GS1 HUG™ (Global Healthcare User Group) “strongly recommends investing in camera-based” systems for automatic identification. As healthcare product manufacturers prepare for global traceability standards, it is important to understand that a successful transition to mass serialization of product packaging involves more than simply reading a barcode on a label; all of the data on the label must be verified for accuracy. In-Sight Track & Trace™ is up to the challenge.

Ready for 21 CFR Part 11 Validation

In-Sight Track & Trace also provides the technical controls needed for FDA 21 CFR Part 11 validation, including secure user authentication and support for automatic audit trail generation. Multi-level permissions can be configured to limit users’ access to only the controls for which they are authorized. Plus, the compact, all-in-one In-Sight “smart camera” systems are easier to maintain and validate for Part 11 compliance than most PC-based machine vision with Microsoft® Windows® operating systems.

Conforms to 21 CFR Part 830 GS1 Validation for UDI

Track & Trace validates human-readable text against GS1 linear and Data Matrix codes meeting the FDA’s Unique Device Identification label requirements for 21 CFR Part 830. With industry leading algorithms, such as OCRMax for reading human readable text and IDMax for reading linear and Data Matrix codes, Cognex Track & Trace offers the highest read rates, while keeping mis-reads at a minimum.

Identification and Data Verification

Networked In-Sight vision systems and In-Sight Track & Trace software are an integral part of a complete identification and data verification solution. Whether you’re looking for a standalone serialized label inspection system, in the early stages of planning your traceability initiative or you have active serialization projects, In-Sight Track & Trace can meet your needs today and equip you for tomorrow’s requirements.

- Read 2-D and 1-D barcodes, including Data Matrix, GS1-128, securPharm, GS1 DataBar and Pharmacode
- Verify correct ID code contents, including compliance with the GS1/securPharm data standard
- Assess Data Matrix code quality at runtime to detect print degradation
- Verify the accuracy of printed text
- Detect label misalignment and skew
- Provide a standard operator interface across your enterprise

Strong OCR: A Key to Pharmaceutical ID

The Cognex OCRMax™ tool is a best-in-class optical character recognition algorithm providing superior read rates of human-readable dates, lot codes and serial numbers.

www.cognex.com/ocr

In-Sight Track & Trace

Track & Trace Validation Documentation for Cost Effective, Easy Integration

Cognex offers supplemental In-Sight® Track & Trace validation documentation based on the GAMP5 (Good Automated Manufacturing Practice) guidelines for the validation of Track & Trace as an automated system in pharmaceutical and medical device packaging. The documentation includes all components required to validate Track & Trace according to a Category 4 system:

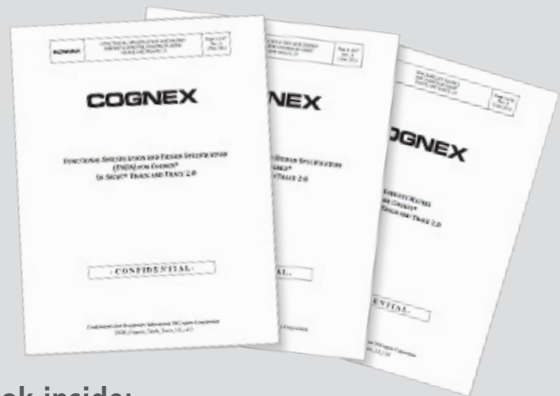
- The Functional Specification and Hardware & Software Design Specification (FSDS) outlining the requested behavior of In-Sight Track & Trace.
- The Installation Qualification & Operational Qualification (IQOQ) documentation for validating the installation and operation of Track & Trace in accordance with FSDS documentation.
- The Traceability Matrix to ensure all requirements have been implemented and tested prior to deployment.

The screenshot shows the In-Sight Track & Trace user interface. The main window displays a product label with tracking information: CIP: 01234567890128, LOT: 12345678A, EXP: 31.10.10, FAB: 09.01.08, UCN: 12345678900000000036. A red box highlights the UCN field with the message "DEFECT ON: UCN:". The interface also shows a statistics table, a batch table, and a configuration panel.

Batch	Operator	Defects
Total	34	18
Good	16	8
Bad	18	10

Batch Name	Actual Batch	New Batch
FAB :	09.01.08	

The In-Sight Track & Trace user interface is easily integrated into PC-based HMIs and custom applications using the Cognex HMI Display Control for .NET.



Look inside:
Download sample documentation today!

View Table of Contents, List of Figures, tool descriptions and sample validation pages at: www.cognex.com/validation

Easy to Integrate, Easy to Use

A touch screen-friendly user interface makes In-Sight Track & Trace easy to configure and operate. Developers can integrate the In-Sight Track & Trace interface into a PC-based HMI or custom application using the included Cognex HMI Display Control for .NET. For a ready-to-deploy solution, In-Sight Track & Trace can also be controlled using the Cognex VisionView® operator interface panel, VisionView VGA adapter, VisionView CE or VisionView PC software.

In-Sight Track & Trace is compatible with most In-Sight Micro, 5000 and 7000 series of vision systems, allowing you to match the resolution and processing speed to the demands of your line. With dozens of models available, there's an In-Sight vision system to meet the price/performance requirements of any serialization application.

In-Sight Track & Trace

Specifications

ID code reading	Read one or two ID codes per label, including Data Matrix, Pharmacode, GS1-128, ITF-14 (Interleaved 2 of 5), Code 39, UPC/EAN, GS1 DataBar (RSS), QR Code, securPharm code	I/O and Communications	TCP/IP data exchange with MES and other software systems PLC data exchange using EtherNet/IP, PROFINET, TCP/Modbus Input text string contains user-configurable batch information Output text string contains user-configurable inspection results Discrete outputs signal for up to 10 pass/fail conditions (requires CIO-1400 or CIO-Micro I/O Module, available separately)
ID code process grading	Assess Data Matrix code quality to detect process changes	Compatibility	In-Sight 7000 series vision systems: 7200, 7210, 7400, 7402, 7410, 7412 In-Sight 5000 series vision systems (32MB or higher): 5100, 5110, 5400, 5401, 5403, 5410, 5413, 5600, 5603, 5604, 5605, 5610, 5613, 5615 In-Sight Micro series vision systems: 1100, 1110, 1400, 1402, 1403, 1410, 1412, 1413 In-Sight Explorer and firmware version 4.8.0 or higher PC with minimum 1GB RAM and Microsoft Windows XP SP3 (32-bit edition) Cognex HMI Display Control in a custom application, VisionView 900 operator interface panel, or VisionView PC software
ID code data verification	Match data in ID codes to expected values Verify data compliance to GS1, securPharm and FDA serialized National Drug Code (sNDC) data standards	Product Contents	In-Sight Track & Trace job file Cognex Audit Message demo application, including sample code Cognex HMI Display Control for .NET, including sample application, source code and API reference documentation In-Sight Track & Trace User Manual and sample images
Optical Character Verification (OCV)	Verify up to six lines of printed text Match printed text to data in ID codes Fixture position of OCV lines using ID code or user-trained pattern (requires In-Sight system with pattern matching tools enabled) Supports up to four user-trainable fonts per label	Part Number	IS-APP-TT
Bundle reading	Read up to 128 ID codes and 4 lines of printed text per image		
Label alignment inspection	Checks for correct horizontal/vertical label alignment and orientation		
FDA 21 CFR Part 11 validation support	Password-protected, multi-level user access controls Double-blind/secondary authorization option Time stamped audit trail messages generated automatically for all user logins, system events and changes to setup parameters Audit messages in XML format, for conversion to compliance database or log file Idle time out automatically logs out after period of inactivity		

COGNEX

Companies around the world rely on Cognex vision and ID to optimize quality, drive down costs and control traceability.

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