Method for Associating Helper Codes to Label Codes for Round Product Serialization

Patent Pending

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Background

The Federal Drug Supply Chain Security Act (DSCSA) mandates the introduction of drug traceability, starting at the lot level and working towards item level.

To maintain the traceability, each level of packaging needs to be appropriately labeled and the Manufacturing Execution Software (MES) needs to be able to manage the aggregation of each level of packing into the next.

This paper describes an improved method for associating Helper Codes to Label Codes in round product serialization applications. Helper Codes are used to facilitate aggregation of round unit bottles to bundles or cases.

See the *LSI Track & Trace White Paper* for a complete description of pharmaceutical serialization & aggregation.

Variable information printed on each label includes human readable Lot Number, Expiry Date, Serial Number and GTIN along with a 2D code (Label Code) representing the human readable data, along with other information. The GTIN is a code which is used to identify the product. The Serial number combined with the GTIN, uniquely identifies each bottle, throughout the supply chain, all the way to the end user. A label is typically applied to each product using a bottle wrap labeler, which wraps the label around the circumference of the product. Once the label is applied to the product, the Label Code can be located anywhere around the circumference of the bottle.

On a typical serialization line, bottles are transported on a conveyor. As the product moves along the conveyor, it rotates, making it impractical to locate and read the Bottle Code with a single scanner. An array of scanners, typically four or six, located at angles to the conveyor (Scan Tunnel), can be used to scan images of the label from multiple angles. A sophisticated "stitching" algorithm can be used to piece the images together into a single image, which approximates the flat label. A second algorithm scans the stitched image to locate and read the 2D code.

To eliminate the need for a Scan Tunnel at every point along the line, where the bottle needs to be identified, a separate 2D code (Helper Code) is printed on either the top or the bottom surface of the bottle. The Helper Code is a serial number, assigned to each bottle, to uniquely identify the bottle during the packaging and aggregation process. Because the Helper code is printed on a nominally flat surface, it can be easily read by a single scanner.

The Label Code and the Helper Code are associated in a database, allowing access to the unique fixed and variable information printed on the label, by simply scanning the Helper Code.

The most commonly used existing technique for associating the Label Code to the Helper Code is to pass the product through a scan tunnel to acquire the Label Code and entering the label code into a FIFO. A short distance downstream the Helper Code is scanned and associated with the oldest Label Code in the FIFO.

Purpose

The improved method creates the database association between the Label Code and the Helper Code at the point of label application, eliminating the need for a Scan Tunnel and the associated capital cost, maintenance cost and points of failure.

Description

The method utilizes a bottle wrap labeler to print variable data on each label and apply labels to products, a control system and multiple scanners for print inspection and data acquisition.

Control System

A Control System, consisting of one or more computers and/or programmable logic controllers (PLCs), coordinates the physical movement of the products and labels on the wrap labeler, with associated data sent to the printers and received from the scanners. The control system generates the Helper Codes to be printed on the products and the Label Codes printed on the labels, transmitting the data to the printers at the appropriate times. It also takes input from the label inspection scanner and the Helper Code scanner, creates the association between the Label Code and the Helper Code for each product and stores the associated codes in a database.
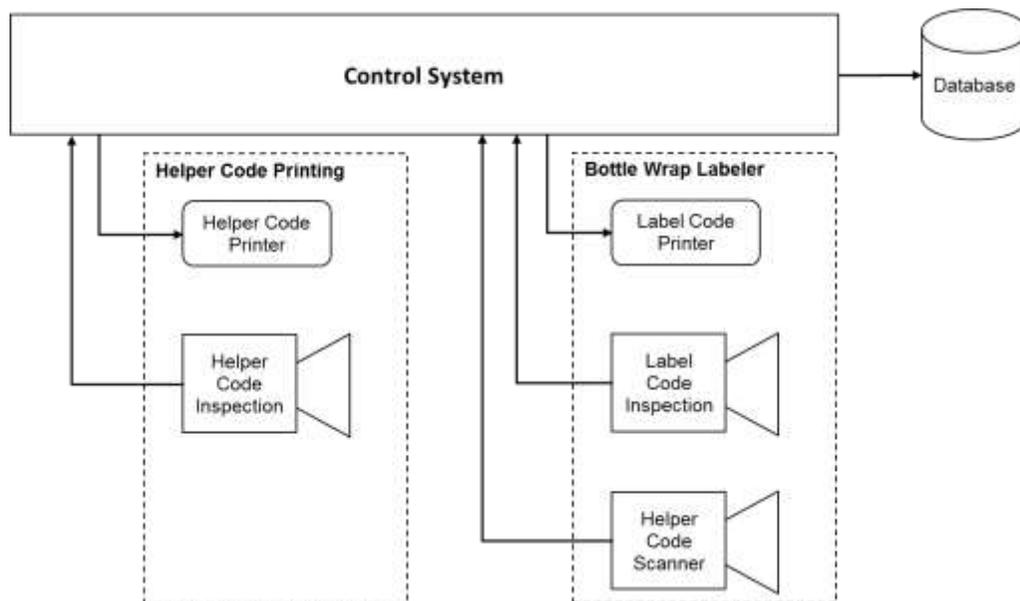
Helper Code Printing

In most cases, Helper codes are printed on either the top surface or the bottom surface of each product, upstream from the Bottle Wrap Labeler. Helper Codes are printed using an inkjet coder, a laser coder or similar printing technology. UV inkjet, which is invisible to the human eye, is sometimes used in applications where concealing the helper code from the end user is preferred. A scanner directly downstream from the printer inspects the printed code. A reject device removes products with invalid or poor quality codes prior to entering the labeler.

In an alternate configuration, the spacing device at the infeed to the labeler can be designed to accommodate Helper Code printing and inspection process.

In all cases, the Helper Code is printed on the product before it reaches the label application point.

Bottle Wrap Labeler

For clarity, it is best to consider the bottle wrap labeler as a collection of subsystems.

1. Product handling
2. Labeling head
3. Wrap applicator

In the simplest configuration, the product handling subsystem is comprised of a conveyor to transport products and a spacing device to create space between products for label application.

The labeling head unwinds the web of labels from a roll, separates each label from the web for application to a product and rewinds the remaining web liner. In a serialization application, the labeling head performs additional functions prior to separating the label from the liner, including; printing variable data on each label and inspecting the fixed and/or variable data on each label.

The wrap applicator rotates each product to wrap a label around the circumference of the product as the label is dispensed from the labeling head.
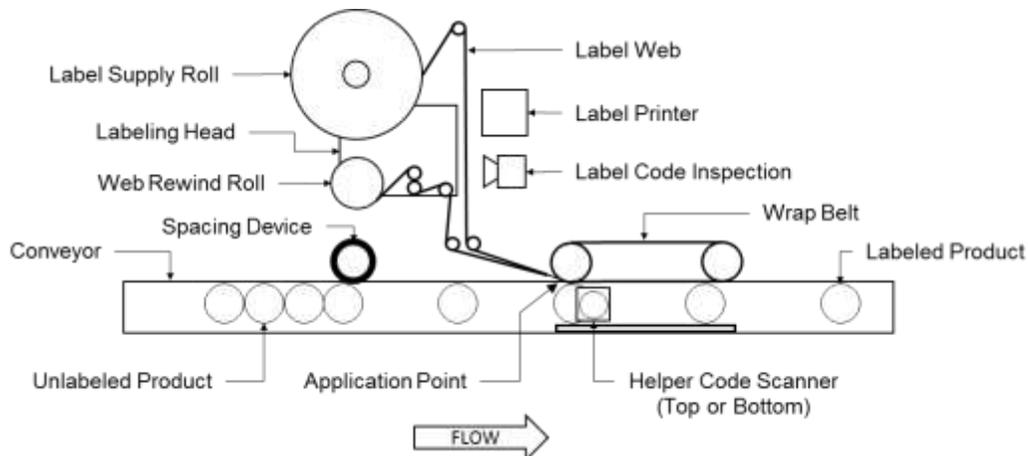
As products pass the application point, the labeling head advances the label web in an intermittent fashion, one label for each product that passes.

After being unwound from the supply roll, the web of labels passes the label printer, where variable information is printed on each label. Label information is typically printed using thermal transfer, laser or inkjet technologies.

The label inspection scanner, immediately downstream from the label printer, reads the printed information, including the Label Code, and transmits the data to the Control System, which verifies that the print quality is satisfactory and that the printed information is correct.

At this point, the Label Code is entered into a shift register. As the web advances, the Label Code is tracked in the shift register.

When the product reaches the application point, it is captured between the wrap belt and a fixed, high friction back-up plate. This causes the product to rotate. The labeling head dispenses the label into the pinch point between the product and the wrap belt. The surface speed of the wrap belt and the labeling head dispense speed are synchronized, such that the label is wrapped around the circumference of the product, as it is dispensed from the labeling head.

While the label is being wrapped around the product, a scanner reads the Helper Code. The Control System associates the Label Code for the label being dispensed with the Helper Code scanned at the dispense point and records the association in a database.
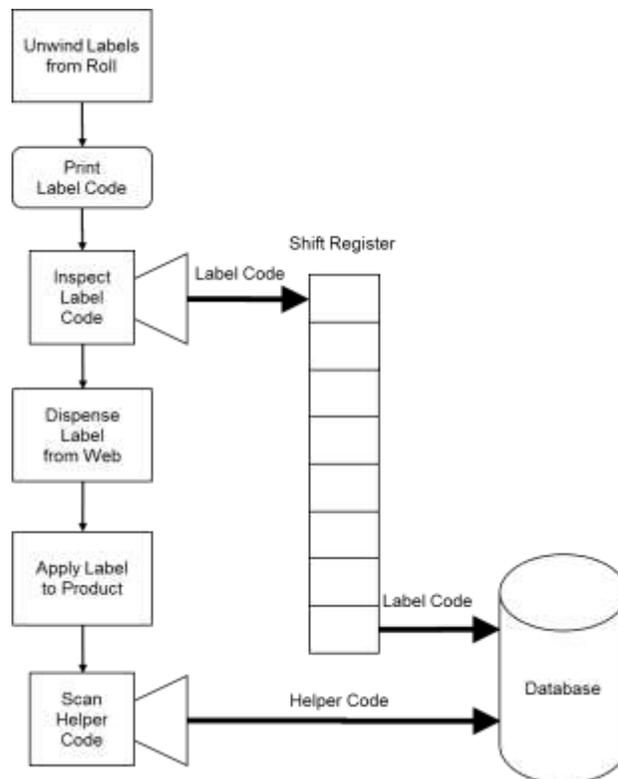
Top or Bottom Helper Codes

A Helper Code can be printed on either the top surface or the bottom surface of the product.

When the code is printed on top, the Helper Code scanner is mounted on an adjustable bracket, located over the wrap belt, such that the Helper Code is scanned as the label is applied to the product.

If the Helper Code is printed on the bottom, the conveyor is split at the point that the product is supported between the wrap belt and the back-up plate. The scanner is mounted on an adjustable bracket under the conveyor, such that the Helper Code is scanned as the label is applied to the product.

Machine Vision

The word scanner is used throughout the discussion above. In most applications, both the Label Code and the Helper Code are 2D codes. Image capture type scanners or machine vision cameras are commonly used for this scanner functionality. In addition to reading the codes, these cameras may provide other functionality such as print quality inspection for the human readable variable data as well as the 2D codes.

Additional cameras or other sensors, located along the conveyor can be used to inspect products to ensure that a label has been properly applied to each product.

Control System

In most applications, the Control System includes a PLC to control the physical functionality of the labeler, along with a Management Executions System (MES), consisting of one or more computers to manage the data sent to the printers, the data received from the cameras and the database that associates Label Codes with Helper Codes.

The MES provides additional functionality including aggregation of products to bundles, bundles to cases and cases to pallets. Most MES implementations also provide rework capability to allow for dis-aggregation and re-aggregation for quality assurance and other purposes.

Product Tracking with Reject and Verification

The PLC labeler control system usually includes functionality for tracking products through the system and rejecting products that fail inspection at any of the inspection points. Reject verification sensors and logic ensures that only products that pass all inspections are delivered to the next downstream process.

Track & Trace from LSI

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LSI seamlessly integrates packaging line equipment, marking and data acquisition devices with Track & Trace software for a complete solution.

LSI Track & Trace system controls are based on the industry standard Rockwell Automation (Allen Bradley) PLC platform.

Solutions are 21 CFR Part 11 Compliant when integrated with compliant serialization management software.

Validation packages (IQ/OQ) are available.

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