# Table of Contents

What is SureLabel™? .................................................................................................................................................. 3
What problems are prevented by SureLabel? ........................................................................................................... 3
Under what circumstances do packaging errors occur? ......................................................................................... 3
Can objects of all types, shapes and orientations be inspected by SureLabel? ...................................................... 3
What type of label inspections are supported by SureLabel? ................................................................................. 4
What tools are available in SureLabel to perform label inspection? ................................................................. 5
Does SureLabel support custom inspections? ......................................................................................................... 5
What is Recipe Management? ............................................................................................................................... 5
Can Recipe Management help me determine that there is a unique pairing of a recipe to a specific label? .......... 8
What is 21 CFR Part 11? ....................................................................................................................................... 9
How does SureLabel support 21 CFR Part 11 Compliance? .................................................................................. 10
What levels of security are provided to protect the integrity of the system? ...................................................... 10
Is event logging available to support system validation? ......................................................................................... 10
What is SureLabel’s standard hardware configuration? ......................................................................................... 10
What options are available for a SureLabel system? ............................................................................................. 11
What types of cameras are supported by SureLabel? ............................................................................................ 11
Does SureLabel support more than just the 2 camera standard configuration? .............................................. 11
What inspection speeds are supported by SureLabel? .......................................................................................... 11
Can SureLabel be deployed on an existing packaging line or only on a new packaging line? ... 12
What is SureLabel™?

SureLabel™ is a powerful and flexible label inspection system that verifies that pre-printed labels have been properly applied on commercial containers. It is a fully integrated turnkey hardware/software system that ensures correct product presentation.

What problems are prevented by SureLabel?

Overall, SureLabel prevents applying an incorrect label to a container. Specifically, SureLabel will prevent:

- The wrong label from being applied to the packaged product
- A missing label
- A poorly applied label
- The wrong pre-printed container or lid from being used

Under what circumstances do packaging errors occur?

Most companies put in place processes and procedures to avoid packaging errors. Even with the best procedures and employees, human error can occur. Here are some of the errors MVC has encountered:

- In most cases, labels come in from an outside vendor, so the wrong labels can be mixed in with the correct labels, unbeknownst to the packager.
- An operator picks up the wrong stack of labels and puts the incorrect stack into the labeling machine without noticing the mistake.
- An operator places the wrong stack of pre-printed container templates at the forming station at the beginning of the packaging line.
- An operator picks up the wrong box of pre-printed lids and dumps it in the hopper.
- The packaging line has not been completely cleared from the previous run.
- Labeler errors cause missing, skewed, or mis-wrapped labels.
- Unauthorized changes have been made to an existing inspection system, with no record of who made the changes, when the changes were made, or what changes were made.

Can objects of all types, shapes and orientations be inspected by SureLabel?

No. SureLabel inspects labels on all types and shapes of containers that are oriented at the point of inspection. Examples are oval containers, such as those used for salad dressings, or
sqrounds used for ice cream packaging. Labels on un-oriented round objects cannot be inspected by SureLabel.

Labels that are still on the backing web and are presented flat can also be verified and inspected by SureLabel before they are applied to a container.

**What type of label inspections are supported by SureLabel?**

SureLabel has a rich set of label inspection tools available for configuration to meet specific inspection requirements. The following label inspection tools are currently available:

- Label presence
- Correct label
- Position and Skew
- Double label
- Flagged label
- Wrinkled label
- Barcode (1D & 2D)
- Optical Character Verification – OCV
What tools are available in SureLabel to perform label inspection?

SureLabel supports a significant number of primary vision tools that may be executed to perform label inspection.

<table>
<thead>
<tr>
<th>Vision Tool</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Match Pattern</td>
<td>Match patterns defined by a rectangular region and verify it matches the trained image pattern to within the specified threshold.</td>
</tr>
<tr>
<td>Match Color</td>
<td>Match a color within a rectangular region and verify it matches the trained image color to within the specified threshold.</td>
</tr>
<tr>
<td>Verify Barcode</td>
<td>Read a barcode within a rectangular region, and verify that it matches the barcode on the trained image.</td>
</tr>
<tr>
<td>Check Skew</td>
<td>Measure the edge-skew between 2 horizontal edges within a rectangular region, and check whether the skew is within the specified limit.</td>
</tr>
<tr>
<td>Check Distance</td>
<td>Measure the distance between 2 horizontal edges, and check whether the distance is within the specified limits.</td>
</tr>
<tr>
<td>Check Intensity</td>
<td>Measure the image intensity within a specified region, and check whether it is within the specified tolerance range of the trained image.</td>
</tr>
<tr>
<td>Verify a String of Characters in a Code (OCV)</td>
<td>Verify that the expected string of characters is present and is legible.</td>
</tr>
</tbody>
</table>

Does SureLabel support custom inspections?

Yes, the primary vision tools are configurable enabling the tools to be combined to create custom inspections. Multiple vision tools and multiple iterations of those tools can be used as necessary to create a custom recipe.

What is Recipe Management?

A recipe is a set of “instructions” that describe the inspections to be performed. An individual label recipe includes the bundling of the appropriate inspection tools, their positions, and their expected values. Recipe management is based on an intuitive operator interface that simplifies the technically complex process of defining these label inspections, permits fast changeover, and manages the results.
Creating a recipe is a simple process that only takes a few minutes. Any user with password access to the configuration settings can access the recipe management interface from the SureLabel home screen:

When creating a new recipe, the user can manually type in a name for the container type or scan its barcode number. SureLabel allows the creation of new, unique recipes for an unlimited number of different container types:
In the recipe creation process, the user creates a “training image,” which is a sample image of a container that would pass inspection:
Then the user applies vision tools to selected characteristics of the training image that will be compared against the corresponding parts of each container that passes through the camera enclosure:

![Image of vision tool application](image)

During a run, any containers that fail to meet the specifications set during this process are rejected by SureLabel and removed from the conveyor. SureLabel can also test recipes to make sure the vision tools are operating properly, and if adjustments need to be made, the recipes can be modified at any time.

**Can Recipe Management help me determine that there is a unique pairing of a recipe to a specific label?**

Yes. The SureLabel system has a unique capability that determines if there is a unique pairing of a recipe to a specific label. This ensures that a recipe is applicable to one (and only one) label.

The Verify Recipe feature provides an easy method of preventing possible inspection errors associated with having multiple recipes having labels that appear similar and may pass inspection under multiple recipes. This is especially useful in situations where there are a large number of different recipes and labels, which could be difficult to keep track of.
manually. It works by comparing the training image of a selected recipe with every other recipe that has been created:

If Verify Recipe recognizes no additional matches, the user will know that the selected recipe is unique; that is, it is the only recipe paired with its label. If there are any additional matches, the user will quickly be able to pinpoint them and determine which recipe(s) need to be modified or deleted. This feature is quick and easy to use and it helps keep the inspection process as error-free and efficient as possible.

What is 21 CFR Part 11?

21 CFR Part 11 is part of a US government regulation for the Food and Drug Administration (FDA) concerning the guidelines on electronic records and electronic signatures. The regulation requires drug makers, medical device manufacturers, biotech companies, biologics developers, and other FDA-regulated industries, to implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data that are (a) required to be maintained by the FDA predicate rules or (b) used to demonstrate compliance to a predicate rule.
How does SureLabel support 21 CFR Part 11 Compliance?

SureLabel is not 21 CFR Part 11 compliant, but rather supplies the tools that enable a system to gain compliance. Enhanced security and log-in control are provided. Image archiving and inspection statistics are logged to provide traceability, history, and an audit trail that aid in system validation. Run size and inspection statistics are saved in a comma-separated-values (.csv) file after each product run.

An IQ/OQ/PQ documentation package is optionally provided with every SureLabel system.

What levels of security are provided to protect the integrity of the system?

Security access permissions are user definable at the Administrator, Supervisor, and Operator levels. The following table lists the supported permissions and depicts a typical access allocation.

<table>
<thead>
<tr>
<th>Permission</th>
<th>Admin</th>
<th>Supervisor</th>
<th>Operator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start/End Run</td>
<td>✓</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>View History</td>
<td>✓</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Select Label</td>
<td>✓</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Offline / Online</td>
<td>✓</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Shutdown App</td>
<td>✔</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Configure App</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Create User</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Create Group</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assign User Permissions</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assign User Password</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Is event logging available to support system validation?

Yes, SureLabel records the following events:
- Log-ins, Log-outs
- Label recipe changes
- Run start time, Run end time
- Label configuration changes
- Parameter changes

What is SureLabel’s standard hardware configuration?

The components that comprise the standard SureLabel system are:
• Image Enclosure which also includes:
  ○ 2 Monochrome Digital Cameras
  ○ Optics
  ○ Custom Lighting Solution
• Operator Workstation/Electronics Closure which also includes:
  ○ PC
  ○ 17” Touch-screen Monitor
  ○ SureLabel Software
  ○ Fan or Vortex Electronics Cooling
  ○ Opto-isolated I/O via Allen Bradley PLC
• Reject Mechanism (Air Required)
• IQ/OQ/PQ Documentation Package
• User’s Manual
• System Schematics

What options are available for a SureLabel system?

Options available for SureLabel are:
• Cameras
  ○ 3 – 8 (base system is configured with 2 cameras)
  ○ Monochrome or Color
  ○ FireWire or GIG-E
• Lockable Rejecter Box
• Product Singulator
• NEMA 4/4X: Stainless steel Food Grade Construction

What types of cameras are supported by SureLabel?

SureLabel supports FireWire and GIG-E cameras. Systems can be configured with monochrome or color digital cameras.

Does SureLabel support more than just the 2 camera standard configuration?

Yes. A SureLabel system may be configured with up to 8 cameras.

What inspection speeds are supported by SureLabel?

Every application is unique which makes it very difficult to calculate a standard speed. The intricacy of a recipe, the number of cameras, camera resolution, and monochrome vs. color
cameras are major contributors to determining inspection speeds. A typical 2 monochrome digital camera SureLabel system will support a speed of 800 ppm.

**Can SureLabel be deployed on an existing packaging line or only on a new packaging line?**

SureLabel has been successfully deployed on both existing packaging lines as well as new packaging lines. It only requires approximately 3’ of line space and never touches the customer product. Installation on an existing packaging line easily fits over the conveyance system.