



Packaging Line Inspection Systems

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Inspection, Integration
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COMPLETE LABEL INSPECTION SOLUTION

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1. Complete Label Inspection

The Lot Number and Expiry Date are not the only critical information printed on product labels. To ensure safe usage of any drug, product description, usage and manufacturing information must be legible for all users and must be printed so that there is no margin of interpretation. For example, last February 2006, Novartis Pharmaceutical recalled 5 lots of Diovan, which amounted to a recall of 239,568 bottles. The recall was a result of product strength and tablet count printing errors on labels.

To avoid such problems and to ensure consistent accurate product labeling, Optel Vision proposes the implementation of a 100% automatic label inspection. This form of inspection will provide more control over the integrity of the printed label information and will essentially render pre inspection of labels unnecessary.

The Complete Label Inspection Station carries out the following inspections as standard features or as options:

- Uniform inspection of all material on label
- Complete text verification with enhanced verification of critical information
- Offset printing error detection (common printing errors)
- **Option** - Comparison of labels with original layout file (XML or PDF), which has been validated by the FDA
- **Option** - Bar code grading according to the GS1 standard (ISO/ANSI).

The following list defines the additional benefits that the automatic Complete Label Inspection Station provides:

- 100% inspection of all labels used in production
- Elimination of risk in using wrong label or wrong version of label
- Reduced inspection time for rolls of labels
- Reduced rework time
- Reduced risk of legal liabilities
- Reduced risk of product recalls
- Reduce human labor for label reconciliation
- Lower operation costs.

2. Solutions for Complete Label Inspection

Complete Label Inspection can be carried out at different steps of the production process. The following are examples of three typical applications.

1. Inspection at printing process

This inspection process works well for Clinical Trial Label Printers since they produce labels with variable information and serialized codes.

The Optel Vision Complete Label Inspection Solution handles database management and is capable of interfacing with printers so that template and variable information can also be managed. This information management can include complete printer control via the vision system by mechanically attaching the system to the printer.

Through controlling the printer via the vision system, a label reprint function can be added. This function eliminates wasting of complete rolls of clinical trial labels and reduces staff interventions.

2. Inspection in label room, prior to sending label roll to product packaging

This solution is ideal for low volume pharmaceutical packaging because it provides a complete label inspection solution at a reduced cost.

The installation of one inspection station will inspect labels at a speed of up to 300 label/minutes. This inspection speed is usually sufficient for supplying label rolls to three packaging lines.

This inspection is carried out on a label winding machine, which can also be supplied by Optel Vision. It is important to note that staff intervention will be required for splicing the web after an error has been detected.

3. On-line inspection on packaging floor

This inspection process also handles overprint verification of Lot Numbers and Expiry Dates. This added inspection capability eliminates the need for other label inspection units and simplifies line operation since all inspections are carried out by one system and are displayed on one interface. In addition, other package integrity inspection capabilities can also be added.

This solution can be retro-fitted onto labelers and Print&Apply equipment.

3. Specifications and Inspection Performance

Since multiple factors influence system performance, exact inspection performance capabilities can only be accurately defined once an application has been evaluated. The following represents a general overview of system performance and is designed to assist customers in selecting system capabilities that relate directly to their specific vision application(s).

Label Inspections Tools

- Optical Character Verification (OCV) Tool detects any mismatched characters and small printing errors in critical printed information such as Lot Number, Expiry Date, Drug Number, Drug Name, Dosage, Drug Strength, and Product Count. The OCV Tool can be used with or without a font library.
- Text Quality Verification (TQV) detects missing characters, missing ink spots and ink stain spots on less critical areas of product labels. The efficiency of the TQV depends on the character size, line thickness and ink quantity used per character.
- Color Presence Verification (gray scale) detects missing color (ie., blob).
- Serialization Tool is used for serialized codes that are found on clinical trial labels, and in anti-counterfeiting codes (ie., Bollino). This tool also offers management of serialized codes from initial printing to inspection and finally to storage.
- Color Verification (**option**) carries out absolute color recognition from an XML file or reference file.
- Optel Vision Inspection Frames carry out accurate verification of logos and special symbols on product labels.
- Linear and 2-D Bar Code Verification Tools verify any linear and 2D symbols.
- Bar Code Grading Tool (**option**) carries out bar code grading according to ISO/ANSI standards.
- The Optel Vision Exclusion Frame is used to isolate and mask any specific area on product labels from inspection.

System Operation

- Editable frames are easily positioned through touch control.
- Variable data can be entered manually or automatically.
- A bar code pencil reader (**option**) can be used for recipes selection at startup.
- The system interface displays the entire product label.
- The system clearly identifies labeling errors through an Error View Box.
- At any time, the system can easily display the last 5 flawed labels on the interface.
- The system offers complete user management with 21CFR Part 11 compliance.

System Architecture

- The system includes a large band scanning device for complete label image integration.
- The system offers a scalable vertical resolution from 1000 pixels to 6000 pixels.
- The system includes a uniform dome LED strobe lighting device with new Flash-LED generation.
- The scalable processing device is completely hardware independent.
- Ethernet and other common communication links are available.
- The system offers complete I/O controls.
- System software is completely expandable.
- System includes complete inspection module for pharmaceutical applications.

Label Coder Control (Optional)

- System can control serialized code generation.
- Complete printer control can be established.
- Template downloads from XML or other file format (to be confirmed with printer capability) can be carried out.
- Variable data (patient number or serialized code) can be transferred with a reprint function.

Other

- Database communication for downloads can be established.
- Label conciliation tools (add/remove), including conciliation reports (statistics), can be added.
- Rewind/Unwind tables are available options.

4. Performance & Guidelines

The following guidelines ensure consistent, complete label inspection accuracy:

Label Height or Web Width

- For label heights of more than 6" (150mm) the 2 camera system (2000 pixels) is strongly recommend.

OCV Inspection

- OCV accuracy is dependent on the number of pixels within each character. Precise OCV requires a minimum of 20 pixels per character.

Text Quality Inspection

- The Text Quality Tool is used to ensure print presence and legibility; it will not detect small character print errors. Therefore, the smaller the font, the less precise the error detection will be.
- TQV accuracy is dependent on the number of pixels within each character. Precise TQV requires a minimum of 10 pixels per character.
- If the height of a character contains less than 10 pixels, thin characters such as 'l's' will be undetectable unless they are in a bold font. If the height of a character contains less than 5 pixels, it will be undetectable.

Bar Code Verification and Grading

- Bar code verification and grading by camera may require high resolution. The amount of resolution also depends on the size of the label and bar code.

Color Inspection

- Gray scale inspection will only detect color presence.
- If a color camera is used, a reference label will have to be used to teach the system the color.

Processing Speed

- Inspection rates will be lower for larger inspection areas.
- Inspection rates will be lower for OCV frames containing numerous characters.
- Depending on line speed and the required resolution, a special Pentium processing board (dual or quad processing) will be required.

Inspection Capabilities In Function of Label and Font Sizes

Label Height <i>(1 or 2 cameras)</i>	Font Size <i>(height)</i>	Pixels per Character <i>1 or 2 cameras</i>	Inspection Capability	
			<i>1 camera (1000 pixels)</i>	<i>2 camera s(2000 pixels)</i>
2" (50mm) (20/40 pixels/mm)	size 4 (1mm) size 6 (1.8mm) 8 + (>2mm)	20/40 36/76 >40/80	TQV OCV OCV	OCV OCV OCV
4" (100mm) (10/20 pixels/mm)	size 4 size 6 size 8 10 + (>2.75mm)	10/20 18/36 20/40 >28/56	TQV TQV OCV OCV	OCV OCV OCV OCV
6" (150mm) (6/12 pixels/mm)	size 4 size 6 size 8 10 12 (3mm) 14 + (3.75mm)	6/12 10/20 12/24 16/32 18/36 >22/44	Undetectable TQV TQV TQV TQV OCV	TQV OCV OCV OCV OCV OCV
8" (200mm) (5/10 pixels/mm)	size 4 size 6 size 8 10 12 14 16 + (>4mm)	5/10 9/18 10/20 14/28 15/30 18/36 >20/40	Undetectable Undetectable TQV TQV TQV TQV OCV	TQV TQV OCV OCV OCV OCV OCV
10" (250mm) (4/8 pixels/mm)	size 4 size 6 size 8 10 12 14+ (>3.75mm)	4/8 7/14 8/16 11/22 12/24 >15/30	Not Recommended	Undetectable TQV TQV OCV OCV OCV
12" (300mm) (3/6 pixels/mm)	size 4 size 6 size 8 10 12 14 16+ (>4mm)	3/6 5/10 6/12 8/16 9/18 11/22 >12/24	Not Recommended	Undetectable TQV TQV TQV TQV OCV OCV

	Recommended Operation
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5. Installation Display

