### Q1: What should you do if the camera is showing as disconnected?

#### A1:

Check the camera's LAN and power cables.

Verify the camera assignment in the software configuration window.

Check the IP address of the CPU or Panel PC's LAN port.

Check the camera's IP address.

## Q2: What steps should be taken if the IO controller is disconnected?

### A2:

Check the IO controller's power supply.

Verify the IP address of the CPU or Panel PC.

Check the IP address of the IO controller.

Ensure the IO slices or modules are properly connected.

# Q3: What should you do if the camera is not flashing when the trigger is received?

### A3:

Go to the software camera settings and click on "Single Grab." If the camera flashes, it means the trigger is not being received from the machine PLC.

Check the physical connection of the light.

Open the software IO settings, go to the troubleshooting section, and click on "LT." The signal should then be high.

# Q4: What should be verified if the primary input for the camera or the trigger for picture grab is not received from the machine PLC?

#### A4:

Verify the software scope view to ensure the trigger signal is being received.

# Q5: What should you check if broken tablets are not being detected?

#### A5:

Check the product threshold.

Verify the tolerance values.

Ensure that tolerances are not bypassed.

Check the Learn history.

Teach a new recipe.

## Q6: What steps should be followed if black spots on tablets are not detected?

A6:

Verify that the black spot is on the top surface of the tablet.

Ensure the spot size is greater than the SPAN tolerance criteria.

If the product is manufactured with black spots, verify that the spot size is larger than the acceptable size.

Check the camera's acrylic cover to ensure it is clean.

Verify that the tolerance setting is enabled.

Check the Learn history of the recipe.

Check the segmentation of the tablet.

#### 21CFR Module

# Q1: What is the purpose of the 21CFR module in SPAN Vision Studio?

A1: The 21CFR module is used for managing user roles, rights, and compliance with regulatory standards like electronic signatures and secure user management.

# Q2: What is the initial login information for the SPAN Vision Studio software?

A2:

The initial login credentials are:

Username: spanuser

Password: \*\*\*\* (Daily password)

#### **How to Enter the 21CFR Module**

### Q3: What is the first step to access the 21CFR module?

A3: Start the SPAN Vision Studio software and log in using the default credentials. Then, click on the "21CFR" button as displayed in the software interface.

## Q4: What should the administrator do after logging in for the first time?

A4: The administrator must create their own user account to use for subsequent logins.

### Adding a User

### Q5: How can a new user be added to the 21CFR module?

A5:

Click on the "User" tab on the right side of the screen.

Click the "Add" button at the bottom of the screen.

Enter the required information in the "User Details" section.

Fill in all fields marked with an asterisk (\*).

Select the appropriate user role.

Generate an electronic signature by clicking "Generate."

Click "Save" to finalize the new user creation.

# Q6: What confirmation does the system provide after successfully adding a user?

A6: The system gives a confirmation message indicating that the user has been created successfully.

### Logging in as an Admin User

Q7: How can the admin user log in after creating a new account?

A7: The admin must first log out from the default "spanuser" account by clicking the Logout button, then log in using the new credentials they created.

### **Editing Default Rights for User Roles**

### Q8: How can default rights for user roles be edited?

A8:

Go to the 21CFR module and click the "Role" tab.

Click the "Edit" button to make changes.

Select the desired role and adjust its rights by selecting or deselecting permissions.

Click "Save" to apply the changes.

Q9: Will changes to default rights affect new users created after the update?

A9: Yes, the updated rights will automatically apply to any new users created after the changes.

### **Editing Policies**

### Q10: How can policies be edited in SPAN Vision Studio?

A10:

Click the "Policy" tab in the software.

Make the required changes to the policy fields.

Click "Save" to apply the updated policies.

### Q11: Do policy changes apply to all users?

A11: Yes, the updated policy settings are applicable to all users.

### **Changing Passwords**

### Q12: What is the process for changing a password?

A12:

Click the "Password" tab.

Enter the old password, new password, and confirm the new password.

Ensure the new password complies with the security policy requirements.

Adding Supervisor/Operator/QA Users

### Q13: What roles can generate an electronic signature?

A13: Only Supervisor, QA, and Admin users can generate an electronic signature.

# Q14: How can rights for a new user be assigned based on an existing user?

A14: By selecting "Configure from existing user," you can replicate the rights of an existing user for the new user.

## Q15: What steps are required to add a Supervisor, Operator, or QA user?

A15:

Click the "User" tab.

Click the "Add" button.

Enter the required information in the "User Details" section.

Select the appropriate role (Supervisor, Operator, or QA) from the dropdown list.

Generate an electronic signature by clicking "Generate."

Assign rights by configuring them manually or using an existing user's configuration.

## **Foreword: Documentation and Safety**

### Q1: What is the responsibility of the staff using these products?

A1: The responsible staff must ensure that the application or use of the described products meets all safety requirements, including compliance with relevant laws, regulations, guidelines, and standards.

## Q2: Why is it important to follow the notes and explanations in the documentation?

A2: Following the notes and explanations ensures proper installation, commissioning, and safe use of the components.

## Q3: Can staff request product modifications based on the documentation?

A3: No, claims for modifications to already supplied products cannot be made based on the data, diagrams, or descriptions in the documentation.

## Q4: How does the documentation address technical or editorial errors?

A4: The documentation may contain errors due to the ongoing development of products. The right to make changes without prior notice is reserved.

Introduction to SPAN Vision Studio Software

## **Q5: What is the primary purpose of SPAN Vision Studio?**

A5: SPAN Vision Studio serves as an operating system for running all SPAN vision applications.

### Q6: When does SPAN Vision Studio initiate?

A6: SPAN Vision Studio loads automatically upon system logon.

### Q7: What hardware does Vision Studio manage?

A7: Vision Studio manages all cameras connected to a specific IPC (Industrial PC).

## Q8: Can Vision Studio integrate cameras from multiple machines?

A8: No, Vision Studio can only integrate cameras installed on a single machine for a specific IPC.

## Q9: Which SPAN Vision applications are supported by Vision Studio?

A9: Vision Studio supports applications such as:

Blisbeat-A: For blister inspection.

Blisbeat-B: For applicators, ampoules, vials, and injection inspection.

Codebeat: For code reading applications.

## Q10: Can Vision Studio host multiple applications on the same IPC?

A10: Yes, multiple applications (e.g., Blisbeat-A, Blisbeat-B, and Foil Code Reader) can be hosted on the same IPC.

#### **General Modules in SPAN Vision Studio**

## Q1: Which modules are accessible to users with appropriate rights in SPAN Vision Studio?

A1: Users with appropriate rights can access the following modules:

Main: 21CFR, Recipe, Manager, Camera, I/O, Config, Batch Manager

Explore: Backup, Share, Utility, Language, About

Report: Audit Trial, Production, Recipe, User

Stuff: Scope View, Video Help, Print Screen

Process: Third-party software connected to SPAN Vision Studio, such as

Notepad, which can be toggled with Vision Studio

Power: Shutdown, Restart, Lock, Logout, Exit

### Q2: What does the 'Main' module include in SPAN Vision Studio?

A2: The 'Main' module includes:

21CFR

Recipe

Manager

Camera

I/O
Config
Batch Manager
Q3: What functions are available in the 'Explore' module?
A3: The 'Explore' module includes the following functions:
Backup
Share
Utility
Language
About
Q4: What are the options available under the 'Report' module?
A4: The 'Report' module includes:
771. The Report Module Melades.
Audit Trail
Production
Recipe
User
Q5: What does the 'Stuff' module offer?
A5: The 'Stuff' module includes:
Scope View
Video Help
Print Screen
Q6: What is the purpose of the 'Process' module in SPAN Vision
Studio?
A6: The 'Process' module allows integration with third-party software (e.g., Notepad) that can be toggled alongside SPAN Vision Studio.

Q7: What power options are available in SPAN Vision Studio?

A7: The 'Power' module offers the following options:

Shutdown

Restart

Lock

Logout

Exit

### **Vision Studio Screen Explanation**

## Q1: What options are available under the 'Recipe' menu in Vision Studio?

A1: Under the 'Recipe' menu, the user can:

Load: Load an existing recipe.

Rename: Rename an existing recipe.

Delete: Delete an existing recipe.

Copy: Copy an existing recipe.

Edit: Edit an existing recipe.

Create: Create a new recipe.

### Q2: Can users view a list of created recipes in Vision Studio?

A2: Yes, users can see a list of all created recipes.

### Q3: What function does the taskbar serve in Vision Studio?

A3: The taskbar is always visible to the user, regardless of the application state. Users can click on the SPAN logo to return to the home screen from any module.

## Q4: What happens when the 'Run' button is pressed in Vision Studio?

A4: When the 'Run' button is pressed, the software will prompt the user for a batch number, and all applications will switch to inspection mode.

### Q5: What is the purpose of the 'Reset Counters On' option?

A5: When the 'Reset Counters On' option is selected and the start button is clicked, the counters for the current recipe and batch number will be reset to zero.

### Q6: What does the 'Reset Counters Off' option do?

A6: When 'Reset Counters Off' is selected and the start button is clicked, the counters for the current recipe and batch number will continue to increment. If a new batch number is entered, inspection will still begin with counter zero, unless 'Reset Counters' is set to 'On'.

### Q7: Who has access to the 'Reset Counters' function?

A7: By default, access to the 'Reset Counters' function is limited to Admin and Supervisor users, though it can be configured.

#### Q8: What does the 'Pause' button do in Vision Studio?

A8: The 'Pause' button allows the user to pause the inspection. During a pause, the user can stop the machine and analyze previously inspected images.

### Q9: What is the function of the 'Stop' button in Vision Studio?

A9: The 'Stop' button ends the current inspection and stops the currently running batch.

## Q10: What options are available through the 'Power' button in Vision Studio?

A10: The 'Power' button provides various options, including:

**Application Exit** 

Logout

Lock

System Restart

Shutdown

# Q11: What does the symbol on the Vision Studio screen represent?

A11: The symbol indicates the current status of the application. There are three possible statuses:

Running

Paused

Stopped

### **Blisbeat - A (Blister Inspection System)**

### Q1: What is Blisbeat used for?

A1: Blisbeat is a blister inspection system developed by SPAN Inspection System. It checks for defected products while they are being packed in blisters on blister packing machines.

## Q2: What types of products can Blisbeat inspect?

A2: Blisbeat can inspect the following types of products:

Single Colored Tablets

Bilayer Tablets

Single Colored Capsules

**Double Colored Capsules** 

**Printed Capsules** 

Soft Gel-Caps

Dragees

White on White Tablets

Gray on Gray Tablets / Capsules

### Q3: What parameters does Blisbeat check for in products?

A3: Blisbeat checks the following parameters:

Dimension

Shape

Color

Color / Black Spot on the top side of the product

Double product in pocket

Foreign Product

Foreign Particles

Product out of pocket

Teach Recipe without Smart Segmentation

## Q4: What are the two methods available for creating a recipe in Blisbeat?

A4: The two methods to create a recipe in Blisbeat are:

Manual Mode

Automatic Mode

#### **Manual Mode**

## Q5: What are the main steps involved in teaching a recipe using Manual Mode?

A5: The main steps for teaching a recipe in Manual Mode are:

Press Machine Grab Button: Run the machine and display captured images.

Image Sorting: Drag images into Empty or Good Image bins based on product quality.

Draw AOI (Area of Interest): Select and draw AOI on the displayed images.

Enter Product Details: Input total blisters, samples per blister, foil type, and color specifications.

Select Special Specifications: Choose options for the product, such as Bi-Layer, Printed, or Transparent Gel.

Proceed to Step 2: Click the manual button to continue.

### **Step 2: Cavity Drawing**

### Q6: What should the user do in Step 2 of Manual Mode?

A6: In Step 2, the user must:

Select the appropriate shape of the cavity (e.g., Circle, Oval, Rectangle).

Enter the total number of cavities in the AOI.

Draw the cavity in the correct position and adjust the zoom for accuracy.

Click 'Search' to find the rest of the cavities.

Add multiple samples if it's a combi-pack type.

### **Step 3: Product Color Selection**

### Q7: How does the user select the product color in Step 3?

A7: In Step 3, the user selects the product color by:

Clicking on a cavity image.

Drawing freehand on the product surface to cover at least 70% of the product area.

Using the software's automatic segmentation to detect the product color.

Erasing or adjusting the drawing if necessary.

Using advanced options such as threshold bars for color segmentation.

### **Step 4: Blister Identification**

#### Q8: What does Step 4 focus on in the recipe teaching process?

A8: Step 4 focuses on identifying the blister positions:

The software will automatically try to find blister positions using smart symmetry.

The user can manually adjust blister positions or redraw them.

The user can reset blister numbers if needed and manually click to reorder the blisters.

#### Step 5: Segment

### Q9: What should the user do in Step 5?

A9: In Step 5, the user should:

Verify that all the products are segmented properly.

Check if all cavities and blisters are correctly positioned.

Ensure that blisters are numbered correctly.

If all checks are successful, click the 'Learn' tab to proceed.

Grab full empty and filled images for learning.

### **Step 6: Finalizing Recipe**

### Q10: What are the final steps in teaching a recipe in Blisbeat?

A10: In Step 6, the user should:

Set the Good Production Limit.

Set the Consecutive Fault Limit.

Choose whether to stop the display/update on errors.

Optionally enable machine stoppage on foreign detection in the base foil.

Click 'Finish' to enter the recipe name and complete the process.

#### **Auto Teach**

## Q1: What types of products are not supported for Auto Teaching mode?

A1: Auto Teaching will not be applicable for the following types of products:

Bi-layer

Rotated Bi-layer

Transparent Gel Capsules

Gems type products

Transparent capsules with granules

Combi-pack blisters

# Q2: What should be ensured when providing images for Auto Teaching?

A2: The following conditions should be met for Auto Teaching:

Symmetry of the blister pack should be present in the AOI drawn by the user.

An empty image should be provided in the empty bin, and a good product image should be provided in the good bin.

No image shifting should occur in the empty and good images.

### Q3: What happens if the criteria for Auto Teaching are violated?

A3: If any of the criteria for Auto Teaching are violated, Auto Teaching may fail, and the system will prompt a message to the user. In such cases, the user should proceed with manual teaching.

### Q4: What steps are involved in Auto Teaching mode?

A4: The steps involved in Auto Teaching are:

Press the Machine Grab button to start the machine.

Review the captured images displayed on the main screen.

Drag the empty image into the Empty Image bin and the good product image into the Good Image bin.

Select "Draw AOI" and define the AOI on the image.

Specify the total number of blisters and the foil type.

Choose the color specification and special product specifications (if any).

Press Auto to automatically detect blisters, cavities, and product colors.

Verify the results and correct segmentation or cavity positions if necessary.

### Q5: What is the Smart Threshold used for in Auto Teaching?

A5: Smart Threshold is an AI-based segmentation method that improves the performance of detecting critical products, especially:

Products with similar color to the cavity.

Products with surface scratches or large printing.

Transparent capsules with varying powder levels or multi-colored granules.

Bi-layer tablets like white-gray on either side.

# Q6: What should the user do if the product color segmentation is not proper during Auto Teaching?

A6: If the product color is not segmented correctly (i.e., the entire product is not highlighted), the user should go to the Threshold Tab and adjust the product segmentation settings as discussed in the manual teaching process.

# Q7: How does the system help with cavity and blister detection during Auto Teaching?

A7: The system uses the Smart Symmetry method to detect blister positions. The user can manually adjust the cavity positions or numbering if needed. They can also use the "Shuffle Blister" button to visualize different blister configurations.

# Q8: What are the corrective actions if the cavity or blister sequence is not correct during Auto Teaching?

A8: If the cavity is not positioned correctly or the blister sequence is incorrect, the user should:

Go back to the relevant step (Step 2 for cavities or Step 4 for blisters) to adjust the positions or sequence as necessary.

### Q9: What happens after the Auto Teaching process is completed?

A9: After completing Auto Teaching, the user should verify the following:

All products are segmented properly.

All cavities are in the correct position.

Blisters are numbered and positioned correctly. If everything is correct, the user can proceed to the "Learn" tab to finalize the training.

## Q10: What is the "Smart Threshold" feature in Manual Mode used for?

A10: The Smart Threshold feature in Manual Mode is used for improving segmentation in critical products, especially when the product is similar in color to the cavity, has scratches, or contains transparent capsules with varying powder content or multi-colored granules.

# Q11: How can the user train the system with images during Manual Teaching?

A11: During Manual Teaching, after segmentation, the user can:

Grab a set of empty and good product images.

Drag the images into the respective bins.

Ensure that the images in the empty bin are completely empty and the good product images are correctly filled.

Verify and correct the segmentation if needed, then proceed to "Learn" to train the system.

# Q12: What should be done if the segmentation results are incorrect during the "Learn" process?

A12: If the segmentation results are incorrect, the user should:

Click "Re-segment" to correct the segmentation.

If the results are still unsatisfactory, the user can discard the changes and start again from the segmentation step.

# Q13: How can the user manage machine settings after the teaching process?

A13: After the teaching process, the user can:

Set the Good Production Limit.

Set the Consecutive Fault Limit.

Enable/disable machine stops on foreign detection or mismatch in punch trigger.

Finalize the recipe by entering a name and completing the setup.

### 1. What is the purpose of Auto Teaching?

Answer: Auto teaching is designed to work for the majority of pharmaceutical products in the market. It is very helpful for the technicians because teach of the product is very easy & detecting product blisters, cavities, and colors are very easily, so user has to just focus on machine operation & not worry about camera.

### 2. What are the criteria for Auto Teaching to work successfully?

#### Answer:

Symmetry of the blister pack should be present in the AOI (Area of Interest) drawn by the user.

The full empty image should be in the empty bin, and the full good image should be in the good bin.

Auto teaching will not apply to Bi-layer, Rotated Bi-layer, Transparent Gel Capsules, Gems type products, transparent capsules with granules, and Combi-pack blisters.

No image shifting should be present in the empty and good images.

### 3. What happens if the criteria for Auto Teaching are violated?

Answer: If any of the criteria are violated, Auto Teaching may fail and prompt a message to the user. In this case, the user will need to switch to manual teaching.

### 4. What are the steps involved in Auto Teaching?

#### Answer:

Step 1: Press the Machine Grab button and run the machine. Once done, captured images will be displayed as thumbnails.

Step 2: Drag the empty and good images into their respective bins, select AOI (Area of Interest) and enable smart segmentation. Then, enter the number of blisters, select foil type, and product specifications.

Step 3: The software will automatically detect cavities, blisters, and product colors after pressing the Auto button.

# 5. What special product specifications can be selected during Auto Teaching?

Answer: The following special specifications can be selected:

Same Color as Foil

**Emboss Print** 

Printed

Bi-Layer

Rotated Bi-Layer

Gems Type

Powder / Granules

Transparent Gel

## 6. What are the corrective actions if the segmentation or cavity detection is incorrect?

Answer:

If the cavity is not in the proper position or does not match the shape and size, the user should return to Step-2 and correct it.

If the blisters are not drawn correctly or numbered incorrectly, the user can go to Step-4 to fix them.

## 7. What is the role of Smart Segmentation in Auto Teaching?

Answer: Smart segmentation uses AI-based technology to improve segmentation accuracy, particularly for challenging products like grey or white items, lozenges, and capsules with granules or powder inside. It enhances the identification of cavities, blisters, and colors.

### 8. What are the tolerances checked during Auto Teaching?

Answer: Several tolerances are checked, including:

Area: Mismatch in the area of segmented product colors.

Length and Width: Mismatch in the major and minor axes of the segmented product.

Convexity: Unevenness in the shape contour of the product.

Shape1 and Shape2: Fine and major shape variations (e.g., broken tablets).

Color: Mismatch in the product's color.

Intensity & Size (Spot): Black or white spots on the product.

Orientation: Incorrect positioning of the product inside the cavity.

### 9. What happens if the tolerance values are exceeded?

Answer: If any of the inspection tolerance values exceed the set limits, the product will be considered rejected.

### 10. How does the system handle foreign particles?

Answer: The system checks for foreign particles in the cavity and on the base foil. It checks for mismatched intensity, color, size, and granules. Any detected foreign particles above the tolerance level will lead to rejection.

### 11. What is the significance of the "Empty" tolerance check?

Answer: The "Empty" tolerance check ensures that the empty cavities are correctly identified. If the mismatch between the empty image and the inspected cavities exceeds the tolerance, the product will be considered non-empty.

### 12. What happens during the "Segment" step of Auto Teaching?

Answer: The segment step allows the user to verify if all products are correctly segmented/threshold, the cavities are in the correct position, and the blisters are numbered properly. If issues are found, the user can go back to the respective steps to correct them.

# 13. What are the parameters checked for defects in Auto Teaching?

Answer: The system checks for various defects, including:

Area: Segmented area mismatch.

Shape: Variations in shape that indicate product defects.

Color: Any color mismatch.

Intensity: Spots or variations in intensity on the product.

Granules: Presence of granules around the product.

Orientation: Misalignment of the product inside the cavity.

# 14. What should be done if the segmentation process is incorrect in Smart Segmentation?

Answer: If segmentation is incorrect, the user must adjust the product alignment and retrain the AI model until the correct segmentation is achieved.

# 15. How is the quality of the product checked once the images are captured?

Answer: After the images are captured, the user must verify that empty images are completely empty, and good images are fully filled. Any discrepancies should be corrected before proceeding with the AI learning process.

### **Scope View - Overview and Features**

### Q1: What is the purpose of Scope View in SPAN Vision Studio?

A1: Scope View is designed for graphical display and analysis of input and output signals from the SPAN IO controller. It helps monitor and track processes over time, assisting with data analysis, troubleshooting, and machine commissioning.

### Q2: How does Scope View aid in troubleshooting?

A2: Scope View allows users to visualize real-time digital input and output signals, such as light, trigger, and machine interlock signals. It eliminates the need for external tools like multimeters for validating SPAN Vision System inputs and outputs.

Scope View Features and Components

### Q3: What is the purpose of the YT Chart in Scope View?

A3: The YT Chart is the display area in Scope View that shows the graphical representation of input and output signals. It provides a time-based view of these signals, with each chart having its own toolbar for display adjustments.

### Q4: What are the main axes used in the YT Chart?

A4: The YT Chart features an input axis, which displays the received input signal for the camera trigger, and output axes, which show the camera trigger, light on output, and the inspection process complete output.

### Q5: What does the 'Inspection Cycle' show in Scope View?

A5: The Inspection Cycle displays a real-time graphical plot of the inspection process for each connected camera, showing the digital trapezoidal waveform for camera trigger, light on output, and inspection completion signals.

Scope View Toolbar Functions

### Q6: What does the 'Play' button do in the Scope View toolbar?

A6: The 'Play' button starts the live display mode, showing the real-time data that is currently being accumulated.

### Q7: How does the 'Pause' button work in Scope View?

A7: The 'Pause' button stops the live display, allowing the user to navigate through the already recorded data without interrupting the ongoing recording.

### Q8: What does the 'Display-Width' option control in Scope View?

A8: The 'Display-Width' option adjusts the time range displayed in the chart. The user can zoom in or out of the data, down to the microsecond range, and change this width using the toolbar or mouse scroll.

### Q9: How does the 'Zoom Horizontal' function work?

A9: The 'Zoom Horizontal' function allows the user to select a new time range by dragging a rectangle across the x-axis of the chart, providing a more detailed view of the selected time span.

### **Camera Settings and Parameters**

### Q10: What is the purpose of the 'Exposure Time' camera setting?

A10: The Exposure Time controls how long the image sensor is exposed to light during image capture, which affects the brightness of the image. Increasing exposure time makes the image brighter, while decreasing it makes it darker.

### Q11: What does the 'Gain' setting do on the camera?

A11: The Gain setting amplifies the signal from the camera sensor, which increases the overall brightness of the image. However, it can also amplify background noise.

### Q12: How does the 'Line Debouncer' setting work?

A12: The Line Debouncer filters out unwanted short input signals, ensuring that only sufficiently long signals pass through and affect the camera's operation.

# Q13: What is the function of the 'Single Grab' button in camera settings?

A13: The 'Single Grab' button captures one image at a time and displays it on the screen.

# Q14: What happens when the 'Continuous Grab' button is pressed?

A14: When the 'Continuous Grab' button is pressed, the system enters continuous image capture mode, displaying the current images being captured by the camera.

### Q15: What does the 'Machine Grab' button do?

A15: The 'Machine Grab' button starts the machine, which triggers the software to automatically capture images based on the machine's operations.

### I/O Settings and Parameters

### Q16: What does the 'Output Duration' parameter control?

A16: The 'Output Duration' defines how long the output signal remains high after being triggered, depending on the set value.

# Q17: What is the difference between 'Timer' and 'Infinite' output in I/O settings?

A17: The 'Timer' output remains high for a set duration before being reset, while 'Infinite' output stays high until the next input trigger is received.

### Q18: What does the 'Output Polarity' setting control?

A18: The 'Output Polarity' determines whether the output signal will be high when the result is accepted or low when the result is rejected.

### Q19: What does the 'Input Spike Filter' do?

A19: The 'Input Spike Filter' helps eliminate unwanted noise in the input signal by setting a threshold for signal duration, ensuring that only valid input triggers are processed.

### Q20: What is the purpose of the 'Light Duration' setting?

A20: The 'Light Duration' setting determines the time that the hood light remains on during the inspection process.

## **Q21: What is 'Trigger Width' in camera settings?**

A21: 'Trigger Width' specifies the duration for the camera's trigger to capture an image during the inspection process.

## Q22: What does the 'Timed Output' setting control?

A22: The 'Timed Output' option generates the accept/reject output after a specified duration following the camera trigger signal.

Generating Backup

# Q1: How do you start the process to generate a backup in SPAN Vision Studio?

A1: To start generating a backup, log in to SPAN Vision Studio, click on the menu icon at the bottom left corner, select "Explore," and then click "Backup."

## Q2: What is the default location for backup files in SPAN Vision Studio?

A2: The default backup location is displayed in the backup window, but you can choose a different location if required.

## Q3: How do you initiate the backup process in SPAN Vision Studio?

A3: To start the backup generation process, click on the "Backup" button.

# Q4: How do you know when the backup has been successfully generated?

A4: Once the backup is successfully generated, a popup will appear confirming the successful backup, and you need to click "OK" to proceed.

# Q5: What should you do to disable a user in the 21 CFR User Management?

A5: Go to the "21 CFR" option, find the user you want to disable, untick the "User enable" checkbox for that user, and then click the "Save" button.

# Q6: How do you check the changes made (such as user disabling) in SPAN Vision Studio?

A6: After making changes, go to the "Audit Trial" and generate a report. The backup generation and user disabling actions will be reflected in the audit trial.

# Q7: What is the next step after generating the backup and disabling the user?

A7: Exit SPAN Vision Studio using the SPAN master password.

### Restoring Backup

### Q8: How do you start the process of restoring a backup?

A8: To restore a backup, go to the Desktop, click on the Windows key, select MySQL, and open MySQL Workbench 6.3.

### Q9: What is the first step after opening MySQL Workbench?

A9: After opening MySQL Workbench, click on the "Database" menu.

### Q10: How do you connect to the MySQL database?

A10: Click "Connect to Database" and then click "OK" to proceed.

## Q11: What credentials are required to connect to the MySQL database?

A11: Enter "root" as the password and click "OK."

## Q12: After connecting to the MySQL database, what should you do next?

A12: Click on the "Server" menu and select "Data Import."

### Q13: What option should you select for importing the backup?

A13: Choose the option "Import from Self-Contained File."

### Q14: How do you select the backup file for restoration?

A14: Browse to the correct location (e.g., D drive > span folder > backup folder > date-wise backup folder > database folder > database.sql file), open the file, and click "OK."

### Q15: What should you do after selecting the backup file?

A15: Click on "Start Import." The import will take a few minutes to complete.

### Q16: What should you do once the database import is complete?

A16: Once the import is completed, close the MySQL Workbench window.

# Q17: After restoring the backup, what should you do next in SPAN Vision Studio?

A17: Start SPAN Vision Studio again, go to "21 CFR User Management," and you will see that the disabled user (e.g., "name-user") is now enabled.

### Q18: What is the final step after the backup restoration is done?

A18: The backup restoration process is complete once the user settings and database have been successfully restored.

#### 1. What is the make and model of the camera used in Blisbeat?

**Answer:** The camera make is SPAN, and the model is C2M1B.

#### 2. What is the resolution of the camera in Blisbeat?

**Answer:** The camera resolution is 1920 x 1200 pixels.

### 3. What type of illumination system is used in Blisbeat?

**Answer:** Blisbeat uses a LED-based side light system (from all four sides of the blister format), operating in flash mode.

### 4. What is the processor type used in the Blisbeat panel PC?

**Answer:** The processor is an Intel Core i7.

#### 5. What is the screen resolution of the Blisbeat panel PC?

**Answer:** The screen resolution is 1366 x 768 pixels.

### 6. What is the operating system of the Blisbeat panel PC?

**Answer:** The operating system is Windows 10 Enterprise, 64-bit.

### 7. What is the size of the camera sensor in Blisbeat?

**Answer:** The camera sensor size is 1/1.2'' with a pixel size of  $5.86\mu m$ .

## 8. What is the focal length of the high-resolution lens used in Blisbeat?

**Answer:** The focal length of the lens is 16mm.

### 9. What is the supply voltage for the illumination system?

**Answer:** The supply voltage for the illumination system is 24VDC.

#### 10. What materials are used for the base foil in Blisbeat?

**Answer:** The base foil materials include ALU-ALU, PVC (transparent), Aclar, PVDC, and PVC Opaque.

### 11. What type of construction materials are used in Blisbeat?

**Answer:** The construction materials are Aluminum HE30 and SS304.

### 12. What is the field of view (FOV) of the camera in Blisbeat?

**Answer:** Generally it is depends on Machine model so field of view can be different like for BQS machine 260x110mm, Elmach 3522 (350x220 mm), IMAPG Excel smart (190x150mm), Romaco Noack 921 (240x168mm), Uhlmann (260x180mm), Rapid Pack (260x150mm) etc.

### 13. What inspection parameters are used in Blisbeat?

**Answer:** Inspection parameters include missing pills, size variation, shape symmetry, convexity, color variation, intensity distribution, foreign objects, cracked tablets, and other detailed checks such as missing parts in capsules.

### 14. What is the supply voltage for the Blisbeat power supply?

**Answer:** The supply voltage for the Blisbeat power supply is 230VAC, 50Hz.

#### 15. What is the rejection output function in Blisbeat?

**Answer:** The rejection output allows settings for polarity (Low/High/Infinite/Overwrite), pulse width, and rejection tracking to be linked to the machine PLC.

#### 16. Does Blisbeat support additional camera integration?

**Answer:** Yes, Blisbeat can integrate with additional systems for bottom inspection (Blisbeat-AS) and code inspection (Codebeat) for static OCR codes on the leading foil.

### 17. Is Blisbeat compliant with 21 CFR Part 11?

**Answer:** Yes, Blisbeat is compliant with 21 CFR Part 11.

#### 18. Does Blisbeat include any supporting documentation?

**Answer:** Yes, Blisbeat includes supporting documents such as IQ, OQ, DQ, and a user manual in soft copy.

### **Defect Detection Accuracy in Tablets**

## 1. What is the defect detection accuracy for area in tablets of size 10mm and above?

**Answer:** The defect detection accuracy for area in tablets of size 10mm and above is greater than 5%.

## 2. What is the defect detection accuracy for area in tablets of size 10mm and below?

**Answer:** The defect detection accuracy for area in tablets of size 10mm and below is greater than 10%.

# 3. What is the defect detection accuracy for area in bi-layer and printed tablets?

**Answer:** The defect detection accuracy for area in bi-layer and printed tablets is greater than 25%.

## 4. What is the defect detection accuracy for length in tablets of size 10mm and above?

**Answer:** The defect detection accuracy for length in tablets of size 10mm and above is greater than 5%.

## 5. What is the defect detection accuracy for length in tablets of size 10mm and below?

**Answer:** The defect detection accuracy for length in tablets of size 10mm and below is greater than 10%.

# 6. What is the defect detection accuracy for length in bi-layer and printed tablets?

**Answer:** The defect detection accuracy for length in bi-layer and printed tablets is greater than 25%.

## 7. What is the defect detection accuracy for width in tablets of size 10mm and above?

**Answer:** The defect detection accuracy for width in tablets of size 10mm and above is greater than 5%.

## 8. What is the defect detection accuracy for width in tablets of size 10mm and below?

**Answer:** The defect detection accuracy for width in tablets of size 10mm and below is greater than 10%.

# 9. What is the defect detection accuracy for width in bi-layer and printed tablets?

**Answer:** The defect detection accuracy for width in bi-layer and printed tablets is greater than 25%.

# 10. What is the defect detection accuracy for broken or chipped tablets for sizes 10mm and above?

**Answer:** The defect detection accuracy for broken or chipped tablets for sizes 10mm and above is greater than 5%.

## 11. What is the defect detection accuracy for broken or chipped tablets for sizes 10mm and below?

**Answer:** The defect detection accuracy for broken or chipped tablets for sizes 10mm and below is greater than 10%.

# 12. What is the defect detection accuracy for broken or chipped tablets in bi-layer and printed tablets?

**Answer:** The defect detection accuracy for broken or chipped tablets in bi-layer and printed tablets is greater than 25%.

# 13. What is the defect detection accuracy for color differences in tablets for sizes 10mm and above?

**Answer:** The defect detection accuracy for color differences in tablets for sizes 10mm and above is greater than 5%.

# 14. What is the defect detection accuracy for color differences in tablets for sizes 10mm and below?

**Answer:** The defect detection accuracy for color differences in tablets for sizes 10mm and below is greater than 25%.

# 15. What is the defect detection accuracy for color spot size in tablets?

**Answer:** The defect detection accuracy for color spot size in tablets is greater than 0.5mm for size 10mm and above, and greater than 1mm for tablets of size 10mm and below.

# 16. Is detection of the same color chipped on non-printed tablets possible in Blisbeat?

**Answer:** No, detection of the same color chipped on non-printed tablets is not applicable (NA).

#### 17. Can Blisbeat detect double tablets?

**Answer:** Yes, double tablet detection is possible if the product does not exactly sit on top of the other product.

# 18. What is the detection accuracy for foreign or extra product/powder in a cavity?

**Answer:** Foreign or extra product/powder can be detected if the product is surrounded from all sides with powder.

# 19. What is the minimum area for foreign or extra product outside the cavity to be detected?

**Answer:** The minimum area for foreign or extra product outside the cavity to be detected is 4 x 4mm (or equivalent area).

## 20. How does Blisbeat detect foreign products or particles of a different color?

**Answer:** Foreign products or particles will only be considered as foreign if they are of a different color compared to the good product.

### 21. Can Blisbeat detect empty cavities?

**Answer:** Yes, Blisbeat can detect empty cavities.

### **Defect Detection Accuracy in Capsules**

# 22. What is the defect detection accuracy for area in non-printed dual color capsules?

**Answer:** The defect detection accuracy for area in non-printed dual color capsules is greater than 10%.

# 23. What is the defect detection accuracy for area in non-printed single color capsules?

**Answer:** The defect detection accuracy for area in non-printed single color capsules is not applicable (NA).

# 24. What is the defect detection accuracy for area in single color printed, soft gel, and transparent capsules with granules?

**Answer:** The defect detection accuracy for area in these capsules is not applicable (NA).

# 25. What is the defect detection accuracy for area in dual color printed capsules?

**Answer:** The defect detection accuracy for area in dual color printed capsules is greater than 10%.

# 26. What is the defect detection accuracy for color spot size in non-printed dual color capsules?

**Answer:** The defect detection accuracy for color spot in non-printed dual color capsules is greater than 1mm.

### 27. Can Blisbeat detect missing caps or bodies in capsules?

**Answer:** Yes, Blisbeat can detect missing caps or bodies in capsules, with specific conditions for single color capsules and dual color capsules.

# 28. Is it possible for Blisbeat to detect cap-body mismatches in capsules?

**Answer:** Yes, it can detect cap-body mismatches in dual color printed capsules, but not in single color printed or soft gel capsules.

# 29. What is the defect detection accuracy for cuts or dents in the outer periphery of capsules?

**Answer:** Blisbeat can detect cuts or dents that are greater than 10% of the area of a good product.

# 30. Can Blisbeat detect foreign products or powder in the cavity of capsules?

**Answer:** Yes, foreign or extra product/powder can be detected if the product is surrounded from all sides with powder.

# 31. What is the minimum area for foreign or extra product outside the cavity in capsules?

**Answer:** The minimum area for foreign or extra product outside the cavity is  $4 \times 4$ mm (or equivalent area).

## 32. Can Blisbeat detect empty cavities in capsules?

**Answer:** Yes, Blisbeat can detect empty cavities in capsules.

### **Security Features**

### 1. Can a user log into Blisbeat without a username and password?

**Answer:** No, the system will not allow login without a username and password.

### 2. Is the minimum password length configurable in Blisbeat?

**Answer:** Yes, the minimum password length is configurable.

### 3. What is the required complexity for passwords in Blisbeat?

**Answer:** Passwords must be alphanumerical and include special characters. The complexity is configurable.

### 4. Can the password expiry period be configured in Blisbeat?

**Answer:** Yes, the password expiry period can be configured, ranging from 1 day to 365 days. A popup message will be generated before the password expires.

### 5. What happens when a password expires in Blisbeat?

**Answer:** The system forces the user to change the password when it expires.

## 6. Can the new password be the same as the old password in Blisbeat?

**Answer:** No, the new password cannot be the same as any of the last five old passwords.

## 7. How many failed login attempts are allowed before a user is locked out in Blisbeat?

**Answer:** The system locks a user account after 3 failed login attempts, although this is configurable (e.g., between 3 to 100 attempts).

#### 8. Who can unlock a locked user account in Blisbeat?

**Answer:** Only the system administrator can unlock a locked user account.

# 9. Can Blisbeat be configured to lock the application after a specific time interval?

**Answer:** Yes, Blisbeat allows configuration of a time-interval for application lock. After this interval, the system will ask for the password to resume.

### 10. Does Blisbeat require a password change on the first login?

**Answer:** Yes, the system enforces a password change on the first login.

### **User Management System and Privileges**

### 11. Does Blisbeat support individual User IDs and passwords?

**Answer:** Yes, Blisbeat provides a system for individual User IDs and passwords.

### 12. Is the username unique in Blisbeat?

**Answer:** Yes, usernames in the application are unique. The system does not allow duplicate User IDs.

### 13. Can user roles be configured in Blisbeat?

**Answer:** Yes, user roles can be configured based on the customer's requirements (e.g., Analyst, Operator, Reviewer, Lab Manager, Administrator, etc.).

### 14. Can Blisbeat generate a report on users and their roles?

**Answer:** Yes, Blisbeat has a function to generate a report of users and their user rights and roles.

### 15. Can Blisbeat generate a report of active and inactive users?

**Answer:** Yes, Blisbeat has a function to generate a report of active and inactive users.

### 16. Can user accounts be deactivated in Blisbeat?

**Answer:** Yes, user accounts can be deactivated but not deleted. Access to deactivation is managed by the system administrator.

#### **Electronic Data**

#### 17. Are electronic data and reports human-readable in Blisbeat?

**Answer:** Yes, electronic data and reports are human-readable and suitable for review and inspection.

### 18. Can Blisbeat perform automatic data backups?

**Answer:** Yes, Blisbeat supports automatic data backup.

### 19. What does the backup in Blisbeat consist of?

**Answer:** The backup consists of data, configuration, and audit trail.

## 20. Can data, configuration, and audit trails be restored in Blisbeat?

**Answer:** Yes, Blisbeat allows the restoration of data, configuration, and audit trails.

### 21. Can end users change the storage of data in Blisbeat?

**Answer:** No, the storage of data is fixed and cannot be modified by end users.

# 22. Is GXP data and audit trail consistent between the software and print in Blisbeat?

**Answer:** Yes, GXP data and audit trails are consistent in both the software and the print.

#### **Audit Trail**

### 23. Is the audit trail feature in Blisbeat always active?

**Answer:** Yes, the audit trail is always ON and cannot be turned off.

#### 24. What actions are recorded in the audit trail in Blisbeat?

**Answer:** The audit trail records the creation, modification, and deletion of batch data (process parameters and results), user and user group data, and master data (e.g., methods, sequences, and recipes).

# 25. What information is included in the audit trail for changes in process parameters or results?

**Answer:** The audit trail includes the username of the user making the change, the old and new values, the date and time of the change, and the reason for the change.

## 26. Does the audit trail capture login and logout details of users in Blisbeat?

**Answer:** Yes, the audit trail captures user login and logout details.

## 27. Are failed login attempts recorded in the audit trail in Blisbeat?

**Answer:** Yes, failed login attempts are reflected in the audit trail.

#### 28. Can the audit trail be modified or deleted in Blisbeat?

**Answer:** No, the audit trail is protected from intentional or accidental modification or deletion.

### 29. What format is the audit trail generated in?

**Answer:** The audit trail is generated in a non-editable format, such as PDF.

### 30. Can the audit trail be printed in Blisbeat?

**Answer:** Yes, the audit trail is printable.

#### 31. Is the audit trail searchable in Blisbeat?

**Answer:** Yes, the audit trail is searchable.

### **Electronic Signature (ES)**

## 32. What information is included in electronically signed records in Blisbeat?

**Answer:** Electronically signed records include the full printed name of the signer, the date and time of signing, and the meaning of the signature (e.g., Reviewed, Approved).

## 33. Is the electronic signature (ES) linked to the electronic record?

**Answer:** Yes, the electronic signature is linked to the corresponding electronic record.

#### 34. Is the electronic signature (ES) unique to user accounts?

**Answer:** Yes, the electronic signature is unique to each user account.

#### 35. Can end users change the date and time in Blisbeat?

**Answer:** Yes, end users can change the date and time of the application and PC without exiting the application. User must login with higher role who have access rights.

#### 36. What is the format of date and time in Blisbeat?

**Answer:** The primary date format is DD/MM/YYYY, and the time format is HH:MM:SS, as required user can change onsite with login SPAN user login ID & password.(24-hour format). This is consistent across both the software and the reports.

## 37. Can the operating system be accessed by end users in Blisbeat?

**Answer:** No, the operating system can only be accessed with a SPAN login, for which users must contact SPAN for a daily password.

# 38. Is the date and time consistent across the software application and the system in Blisbeat?

**Answer:** Yes, the date and time remain the same across both the software application and the system.

### 1. Issue: Unable to Connect with Database Server

Q: What can cause issues connecting to the database server?

A:

- 1. If MySQL password has expired, reset the password.
- 2. If MySQL service is not running, reinstall the MySQL executable.
- 3. If MySQL services are off, reset the MySQL password.

### 2. Issue: Unable to Load Recipe Image

Q: What can prevent the loading of a recipe image?

A:

- 1. Hardware change (such as camera replacement).
- 2. Camera assignment group has changed.
- 3. Camera swapped at an assigned station or due to LAN swapping.
- 4. Changes in application software.
- 5. If a recipe is taught with one camera and two cameras are enabled.

## 3. Issue: Unable to Save Recipe Image

Q: Why might saving a recipe image fail?

A:

- 1. The software login is not with an administrator account.
- 2. User Account Control (UAC) settings are not configured properly; it should be set to "Never Notify."

### 4. Issue: Data Transfer Speed is Too Slow

Q: What could cause slow data transfer speeds?

A:

1. Hardware changes, such as altering the camera position.

- 2. LAN cable is changed to a type other than CAT6.
- 3. Incorrect LAN driver updates (driver not matching the camera).
- 4. Improper basic settings like Jumbo packet size, or UAC settings not configured to "Never Notify."

### 5. Issue: Unable to Connect with SPAN IO controller

Q: What might prevent a connection to the SPAN IO controller?

- 1. IO controller is not powered up.
- 2. If there was a power breakdown followed by immediate power-up, the IO controller may be in configuration mode.
- 3. I/O slice is not properly connected.
- 4. Physical connections are incorrect.
- 5. LAN cable is interchanged.
- 6. IO controller is not configured.
- 7. IO controller is not connected to the system software.

#### 6. Issue: Unable to Connect with SPAN Device Pointer

Q: What can cause issues connecting with the SPAN device pointer?

A:

1. Contact to SPAN team for the resolution.

support@spansystems.in & service@spansystems.in

#### 7. Issue: Grab Timeout

Q: What could cause a grab timeout error?

A:

- 1. Check the physical wiring.
- 2. Verify the LAN cable and port.
- 3. Ensure the LAN port driver is up-to-date.
- 4. Jumbo packet value should be set to 9014.
- 5. Windows firewall could cause this issue if enabled.

### 8. Issue: MySQL Server Has Gone Away

Q: How do you resolve the "MySQL server has gone away" error?

- 1. Go to the C drive and enable hidden folders.
- 2. Navigate to the Program Data folder and open MySQL.
- 3. Open the MySQL server 5.7 folder.
- 4. Right-click on the My.ini file and select "Edit."
- 5. Scroll to the bottom and add the line wait\_timeout = 2147483.

### 9. Issue: Extra Secondary Inputs (Punch Triggers) Mismatch

Q: What could cause an extra secondary input error in punch triggers?

- 1. Check the machine's secondary input configuration.
- 2. If the mechanical sensor is disturbed, this could happen.
- 3. Verify machine settings, particularly the camera to punching tool (cutting count) settings.
- 4. Perform a total power shut down and restart.
- 5. Ensure the mechanical sensor is properly mounted and not loose.

### 10. Issue: Timed Output Value of I/O Settings is More Than Zero

Q: What should be done if the timed output value of I/O settings is greater than zero?

#### A:

The "Timed Output value" should be set to zero, otherwise user can face challenge accept/reject blister mismatch.

### 11. Issue: OpenDevice Failed. GC\_ERR\_ACCESS\_DENIED

Q: What causes the "OpenDevice failed. GC\_ERR\_ACCESS\_DENIED" error?

#### A:

- 1. The Baumer camera IP might have been removed from the Baumer application.
- 2. Check the basic settings and ensure power management is disabled.

- 3. The LAN driver for Baumer camera should be "Intel," not "Basler."
- 4. Ensure the PLC side LAN is connected to the correct port and dip switch positions are set properly.
- 5. If you click "OK" to this message and log into the SPAN software, the camera settings window and all tabs may be disabled.