Installation of a New Cognex Vision System for Quality Inspection on PDS (ATS-5889) Machine at Surgical Device Company in the Eastern Region of Puerto Rico

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Abstract *— There is a 4-6% scrap on PDS (Protected Disposable Scalpel) machine actual vision system. It is important for the company to manage more efficiently and try to reduce scrap percentage through the entire process of the blades and scalpels fabrication, to be able to sustain in the surgical business and prevent losses of significant amounts of money due to client loss. It is possible to reduce scrap on this machine at this specific station since we are having false rejects due to actual vision system reduced capability. Using a new Cognex [1] vision system it is possible to reduce scrap having a better image of the product, eliminating false rejects. After analysis it is possible to say that 2013 year was the year with more scrap related to the PPT PDS Vision System. Another observation is that the major causes of scrap were the over buffing and stains on the scalpel blade. This new Cognex Vision System could be used on most of the applications for visual inspection in the manufacturing companies.*

Key Terms *— Cognex Vision System, Over Buffing and Stains, Scrap Reduction, Surgical Device Company Las Piedras, PR.*

INTRODUCTION

During the last year, inefficiencies on the Vision System of PDS machine is affecting equipment's production daily rate. Existing limitations on camera tooling is creating false rejects on the automatic visual inspection station. Based on an average yearly volume of 14.5MM blades for the PDS, with an average of 5% overall scrap, out of which 20% is attributed to false rejects due to limited camera tooling, an average amount of 145,000 scalpels, per year, are being discarded due to existing inefficiencies on the PDS Vision system. CPA was created and presented to the company for the amount of twenty seven (27,000) thousand dollars.

Funds were requested to:

1. Upgrade the existing PPT vision system with a Controllogix System migration to a new Cognex Camera.
2. Replace existing HMI computer.
3. Programming the new camera with PLC[3] program of the PDS machine.

This new vision system will eliminate the scrap associated with inefficiencies on the exiting camera tooling, which translates to a minimum average yearly saving of $30,000. In addition, the Cognex program tool's are more user friendly than the current PPT's.

Another alternative is to migrate the entire control system SLC 500 PLC to a controllogix PLC [2], which is very costly. It will be more beneficial to migrate only the controllogix program and install the new camera since the effect on the output of the machine will be the same, and the cost difference between projects is significant. The solution being proposed is the most cost effective for the business.

This change is necessary for the reduction of scrap related to the false rejects. The major risk lies on not performing this change and start to see an increase of scrap due to lack of tooling on the currently system, causing the machine's output to be affected.

To complete Full vision system migration will be needed machine time for 1 week in order to execute a full replacement of the existing PPT [3] Camera System and HMI computer for New Cognex Vision system with new HMI. VIP will be accounted for false rejects; current vision system uses obsolete and non user-friendly tooling system compared to new Cognex software tooling.

BACKGROUND INFORMATION

This change affects the assembly process for the Protected Disposable Scalpel System at ATS-5289 Automatic Assembly Machine [4]. This equipment is located in the Assembly and Pack area at Surgical Device Company, Las Piedras, PR facility. The Installation, Operational and Performance Qualification covers the Cognex Camera Vision System Insight 5100, Installed by DAP Advance Automation Services.

Process Description

The Bard-Parker Protected Disposable Scalpel consists of a blade handle, a blade and a shield (as per Figure 3). The process operation to be validated is defined in the following flowchart. This protocol will validate installation and capability of inspection of the equipment after the replacement of the PPT vision system by a Cognex vision system at the PDS Automatic Assembly Machine (ATS-5289). The process flow will remain the same.

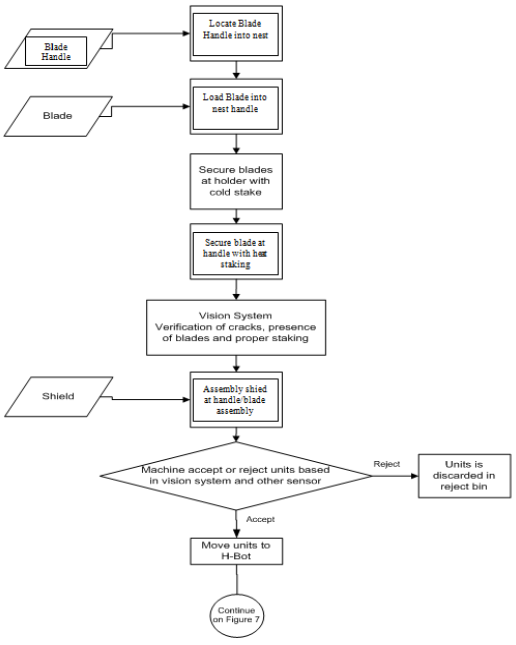


Figure 1 –Process Flowchart – continue on figure 2

Figure 1
Process Flow Chart

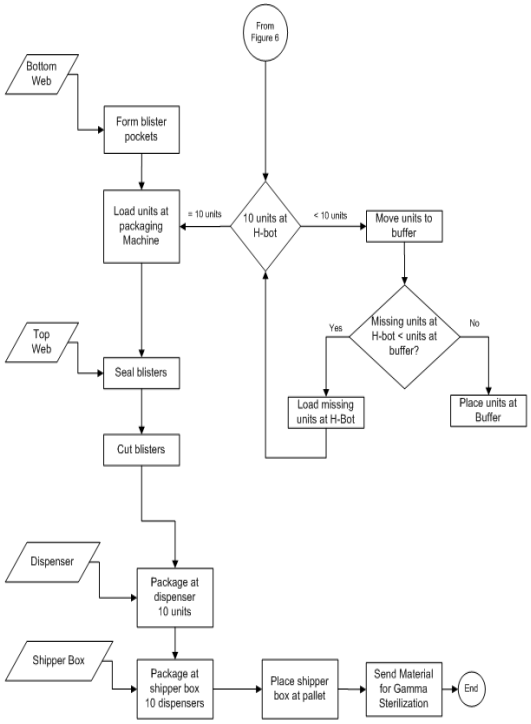


Figure 2 –Process Flow Chart – from figure 1

Figure 2
Process Flow Chart Cont.

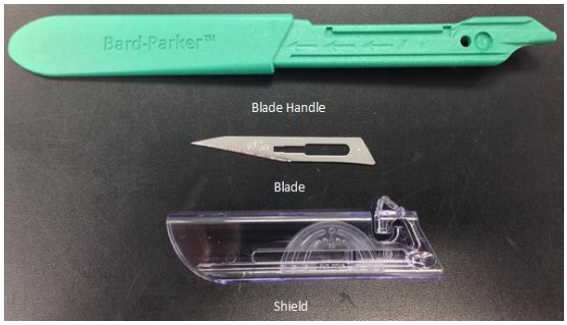


Figure 3
Scalpel Components

METHODOLOGY

This section provides a detailed plan of how the project will be performed. This validation will show, through documented evidence that the Cognex Camera Vision System Insight 5100, is capable to detect when defects of crack blades, insufficient staking and missing blades are present.

Validation Strategy

Installation Qualification: An IQ will be performed for the PDS Assembly Machine (ATS-5289) to ensure the Cognex Vision System, with all

its components, have been installed properly. During the IQ the Cognex In-Sight 5100 camera with a new HMI for the vision system will be installed.

Operational Qualification: An OQ will be conducted to establish evidence that the Vision System, with all its components, can consistently discard the following defects:

1. Crack on blades
2. Improper large staking
3. Improper small staking
4. Missing blade

Sampling Plan: The challenge to the system will consist of 80 good units and 10 units per each defect inspected by the machine and three replicas as indicated below:

Table 1
MSA Method

MSA	Samples Size	Replica
Good	80	3
Crack on blade	10	3
Insufficient Large	10	3
Insufficient Small	10	3
Missing Blade	10	3

Performance Qualification: A PQ will be conducted to establish evidence that the Vision System, with all its components, can consistently discard all defects on a normal production basis. DHR from PQ run will be attached to the validation protocol.

Acceptance Criteria

Process Acceptance Criteria:

1. Production: Minimum interruptions due to conditions attributed to Visual Inspection System performance.
2. Quality: Unaltered product quality. Acceptable results for quality audits, visual inspections and functional test.
3. Safety: Visual Inspection process does not pose harm to operators nor damage to the product.
4. Documentation: All necessary documentation is readily accessible and up-to- date.

IQ acceptance criteria: Training shall be performed to all personnel involved with the execution of this protocol explaining their participation on the validation. Installation of all Vision system components will be completed. Wiring diagrams will be provided. All pertaining manuals for the vision system components will be provided. PLC will be programmed. Copy of the PLC program will be provided. Preventive maintenance will be updated if necessary to include maintenance suggested by the supplier if is other than the one used on the PPT vision system. PM tasks (if applicable) and suggested spare parts list will be provided to be entered to the IFS system. Evidence will be included to show they were entered in IFS.

OQ acceptance criteria: Training shall be performed to all personnel involved with the execution of this protocol explaining their participation on the validation. An MSA will be submitted as part of the OQ exercise and it should meet a GR&R of 10% or less. A total of one hundred and twenty (120) units will be inspected for the following requirements. Each inspection will be repeated three (3) times.

1. Crack on blades
2. Improper large staking
3. Improper small staking
4. Missing blade

PQ Acceptance Criteria: Training shall be performed to all personnel involved with the execution of this protocol explaining their participation on the validation. All in-process inspections and quality audits are to be documented as per the normal operating procedures and documented on the DHR. Copies of these DHRs will be included on the validation report. Acceptance Criteria for Performance Qualification will be based on in process inspection, documented on the DHR, and quality visual inspections after PQ completion included on validation report.

Control Plan: Procedures should be followed as required under normal production runs.

Deviation Handling: Any deviations that may occur during the validation runs will be documented using appropiate form. If generated, it will be investigated and resolved prior to report approval.

Installation Qualification

Prerequisite Steps: Personnel to conduct the IQ will be identified and trained and it will be documented on the validation report.

Equipment:

1. PDS Automatic Assembly Machine (ATS-5289).
2. Cognex Camera In-Sight 5100.
3. Lent 25mm with a 5mm expansion / CCS light[5].

Materials:

1. N/A

Installation Work: Inspect all mechanical components. Ensure all components have arrived. Ensure all bases can be mounted to the machine and they align with the transfer conveyor. All major components must meet specification. Perform all hardware installation:

1. Cognex In-Sight 5100 camera.
2. HMI

Manufacturer's instructions for the different vision system components will be included in the validation report. Perform all wiring needed between the Assembly Machine and the Vision System components. Wiring diagram will be included in the validation report. PLC program will be completed with all its logics. PLC program will be included in the validation report.

Maintenance Procedure: New maintenance activity if required will be provided to be entered to the IFS system using the appropiate form. As part of maintenance, any new part that needs to be added to IFS will be included in the validation report.

Collection of Data: Qualified personnel involved in the execution of the protocol will document all data, using the appropriate attachments. This data will be included in the validation report.

Review of Data: Qualified personnel, involved in the execution of the protocol, will review the data.

Disposition of Product: No Product will be produced during the IQ.

Complete IQ Report: A completion IOQ report memo will summarize all the result. All documents will be completed and signed. This memo will be kept as part of the validation report. All attachments, need to be furbished to consider the IOPQ exercise completed.

Operational Qualification

Prerequisite Steps: Personnel to conduct the OQ will be identify and trained and it will be documented on the validation report. Successful completion of IQ. An IOQ completion memo will be submitted so it is not a pre-requisite to have an interim IQ report approved prior to OQ execution.

Equipment:

1. PDS Automatic Assembly Machine (ATS-5289).
2. Cognex In-Sight 5100.

Materials:

1. Protected Disposable Scalpel Handle #3, (#8363362).
2. Blade Size: 10, 11, 15
3. Small Shield (X3991AAAL)
4. Samples will be prepared as follow: Generate 10 broken blades. Turn on the ATS equipment. Open the machine door and place 10 handles under pallets at station heat-stake stations. Pick ten stainless steel blades, sizes 10 11 or 15, and using a cutting pliers break the blade. Place the blades at each handle. On station 9 manual mode screen (heat-stake station) select the piston down button of stations 9 and 10. This will activate the station piston performing heat-stake to units with broken blades. Remove all units from the machine nest and placed on a plastic box and identifying them as crack blades.

Generate 10 missing blades. Turn on the ATS equipment. Open the machine door and place 8 handles under pallets at station heat-stake stations. On station 9 manual mode screen (heat-stake station) select the piston down button of stations 9 and 10. This will activate the station piston performing heat-stake to units. Remove all 8 units from the machine nest and placed on a plastic box and identifying them as missing blades. Add two handles from the bowl feeder.

Generate 10 insufficient small heat-stakes and 10 insufficient large heat-stakes. To make them, turn on the ATS equipment. Open the machine door and place 10 handles under pallets at station heat-stake stations. Pick ten stainless steel blades and place them on nests under stations 9 and 10. Reduce the stake pressure to 35. On station 9 manual mode screen (heat-stake station) select the piston down button of stations 9 and 10. This will activate the station piston performing heat-stake to units. Remove all ten units from the machine nest and inspect them for improper staking. Segregated which staking was not properly done (small or large) and segregate the units. Repeat this step until 10 or more units of each defect are available. Put on a plastic box and identifying them according it defect (small or large) heat stake insufficient.

Define OQ Runs: A total of a hundred and twenty (120) packages will be inspected for each of the requirements. Each inspection will be repeated three (3) times with different units following the same distribution of good/bad units. Acceptable and unacceptable samples will be used. The groups for this test will be prepared with the following distribution of good and defective units:

Table 2
MSA Method

MSA	Samples
Good	80
Crack on blade	10
Insufficient Large Heat Stake	10
Insufficient Small Heat Stake	10
Missing Blade	10

Prepared samples will be cycle through the machine. Run one cycle of the machine and when machine stop, removes the units from the heat stake station and substitute them with the units prepared following the matrix on the validation report. Make a single cycle on the machine and verify the results of the system. Indicate the results obtained during the inspection. This challenge will be documented on the validation report. Remove units already inspected by the vision system and replace it with a handle without blade. Place the rejected unit on an identified bins with the units status (good, crack, missing blade etc.) to be used it again. Repeat steps 9.4.5 to 9.4.8 until 12 cycles were obtained. Repeat steps 9.4.5 to 9.4.8 until 2 more replicas are obtained for a total of 360 units tested. These challenges will confirm the vision system is capable to discriminate between acceptable and unacceptable parts. Purge the machine and perform 100% inspection on all blades assembled on the challenge. Document results on attachment #10. This challenge will confirm that the bad units are rejected at the end of the process.

Collection of Data: Qualified personnel involved in the execution of the protocol will document all data, using the appropriate attachments. This data will be included in the validation report.

Review of Data: Qualified personnel, involved in the execution of the protocol, will review the data.

Disposition of Product: No Product will be produced during the OQ.

Complete OQ Report: A completion IOQ memo will summarize all the results, conclusions, and detailing recommendations on how to proceed. All documents will be completed and signed. All attachments, as per section 8.9, 9.9 and 10.9 of this protocol, need to be furbished to consider the IOQ exercise completed.

Performance Qualification

Prerequisite Steps: Personnel to conduct the PQ will be identify and trained, and it will be documented on the validation report. Successful

completion of IOQ and IOQ completion memo approved prior to PQ execution.

Equipment:

1. PDS Automatic Assembly Machine (ATS-5289).
2. Cognex In-Sight 5100

Materials:

1. Protected Disposable Scalpel Handle #3, (#8363362).
2. Blade Size: Any Size
3. Small Shield (X3991AAAL)

Define PQ Runs: PQ runs will consist of three (3) twenty five (25k) unit lots, which will be processed through consecutive shifts based on current production schedule. Additional quality inspection, after PQ completion, will be performed by qualified personnel, as per table below. Sample size determined for upper 90% confidence bound on true defect rate.

Table 3
KPOV's

Characteristic	AQL	Sample Size	ACC/REJ
Broken Blade	0.25%	920	0/1
Non-conforming Heat Stake	0.65%	354	1/2
Missing Blade			1/2

Inspection results will be documented on the validation report. machine parameters will be set as per PBS-001. All production data will be documented on respective DHR. DHR will be included on the validation report.

Collection of Data: Qualified personnel involved in the execution of the protocol will document all data, using the appropriate attachments. This data will be included in the validation report.

Review of Data: Qualified personnel, involved in the execution of the protocol, will review the data.

Disposition of Product: All units produced during the PQ will remain on hold until validation activities have been completed. PQ lots will be released for sale once all documentation has been approved.

Complete PQ Report: A completion IOPQ Report will summarize all IQ, OQ, and PQ results, conclusions, and detailing recommendations on how to proceed. All documents will be completed and signed to consider the IOPQ exercise completed.

RESULTS AND DISCUSSION

MSA Results

Run #1 Summary Report:

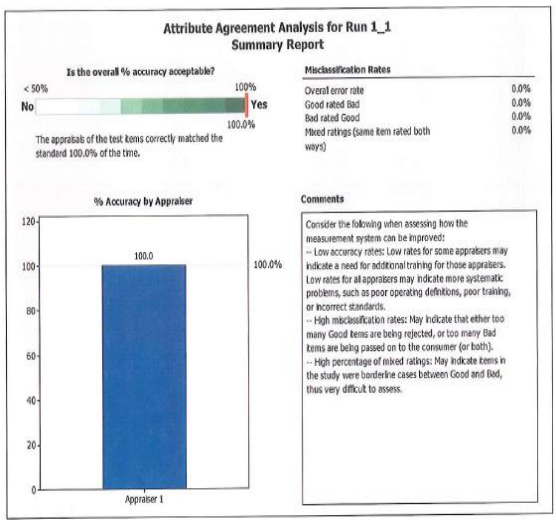


Figure 4
Summary Report

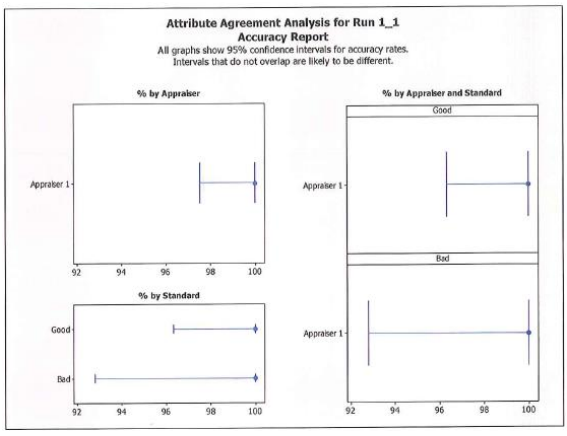


Figure 5
Run #1 Accuracy Report

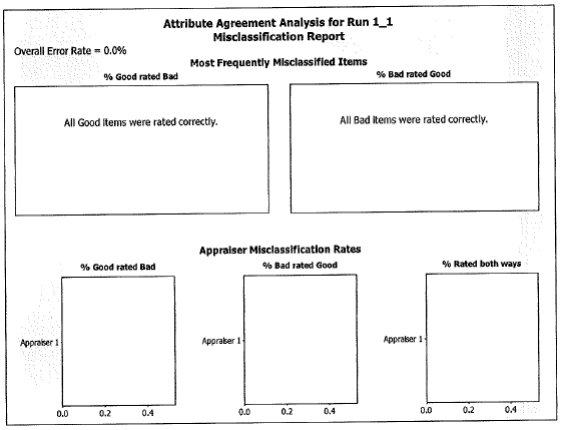


Figure 6
Run #1 Misclassification Report

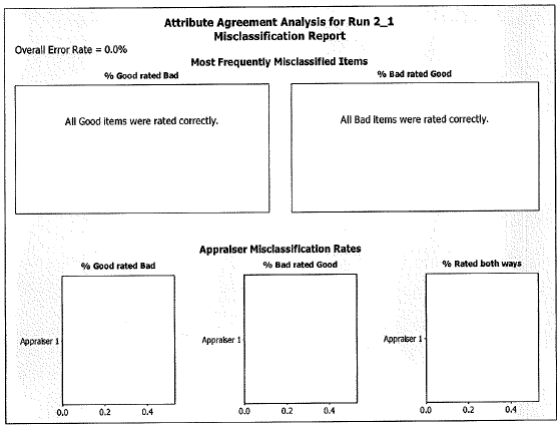


Figure 9
Run #2 Misclassification Report

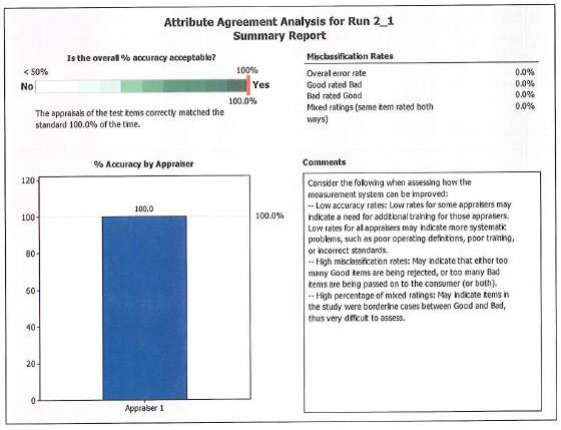


Figure 7
Run #2 Summary Report

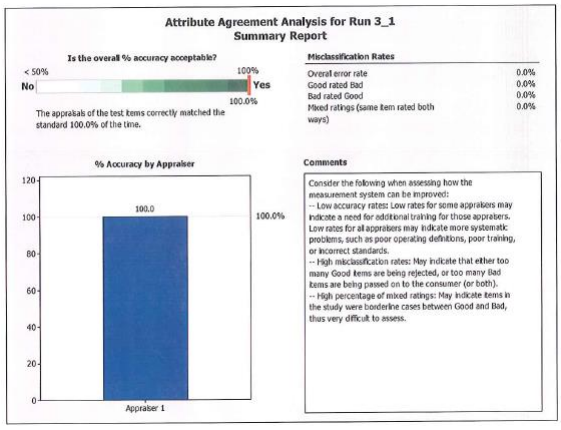


Figure 10
Run #3 Summary Report

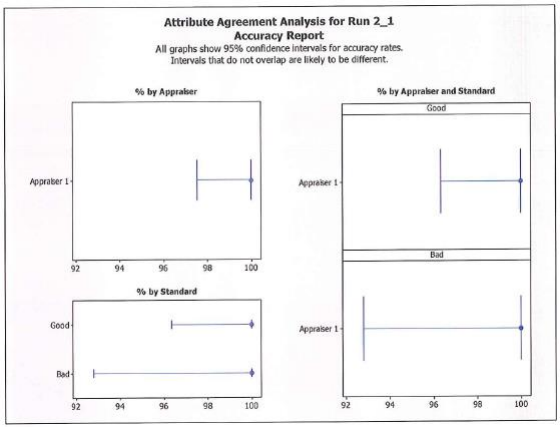


Figure 8
Run #2 Accuracy Report

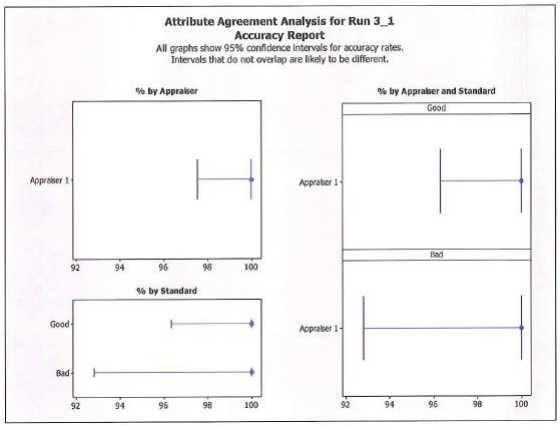


Figure 11
Run #3 Accuracy Report

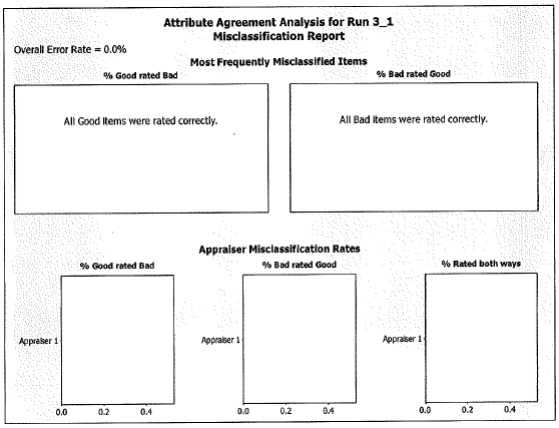


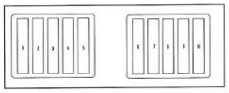
Figure 12

Run #3 Misclassification Report

MSA for Vision System Verification

Vision System Verification

The number inside the matrix (2-5) represents the kinds of defects that the vision system can detect.
- 2 = Crack Blade
- 3 = Improper Small Heat Stake
- 4 = Improper Large Heat Stake
- 5 = Missing Blades



Representation of nest positions at machine

Machine Index	Nest Number 1	2	3	4	5	6	7	8	9	10	Rejected Nest by Vision System
1	-	4	-	-	3	-	-	-	5	-	2-5-9
2	3	-	-	-	5	-	2	4	-	-	1-5-7-8
3	-	2	-	-	-	-	-	-	-	5	2-10
4	-	3	-	-	-	5	-	2	4	-	2-6-8-9
5	5	-	2	-	3	-	4	-	-	-	1-3-5-7
6	-	5	-	2	4	-	-	3	-	-	2-4-5-8
7	4	-	-	3	-	-	-	-	-	2	1-4-10
8	-	-	5	-	2	4	-	-	3	-	3-5-6-9
9	-	-	3	-	-	-	5	-	2	4	3-7-9-10
10	-	-	-	5	-	2	4	-	-	3	4-6-7-10

Comments: Blade Size #10

Performed By/Date: 02-20-14

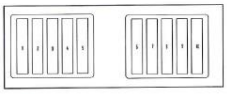
Reviewed By/Date: 02/20/14

Figure 13

Run #1 Documentation

Vision System Verification

The number inside the matrix (2-5) represents the kinds of defects that the vision system can detect.
- 2 = Crack Blade
- 3 = Improper Small Heat Stake
- 4 = Improper Large Heat Stake
- 5 = Test Aborted (no blade)



Representation of nest positions at machine

Machine Index	Nest Number 1	2	3	4	5	6	7	8	9	10	Rejected Nest by Vision System
11	2	-	-	-	3	-	-	-	-	-	1-5
12	-	4	-	-	-	-	-	-	5	-	2-9

Comments: Blade Size #10

Performed By/Date: 02-20-14

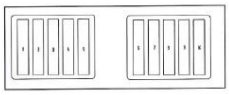
Reviewed By/Date: 02/20/14

Figure 14

Run #1 Documentation Cont.

Vision System Verification

The number inside the matrix (2-5) represents the kinds of defects that the vision system can detect.
- 2 = Crack Blade
- 3 = Improper Small Heat Stake
- 4 = Improper Large Heat Stake
- 5 = Missing Blades



Representation of nest positions at machine

Machine Index	Nest Number 1	2	3	4	5	6	7	8	9	10	Rejected Nest by Vision System
1	-	4	-	-	3	-	-	-	5	-	2-5-9
2	3	-	-	-	5	-	2	4	-	-	1-5-7-8
3	-	2	-	-	-	-	-	-	-	5	2-10
4	-	3	-	-	-	5	-	2	4	-	2-6-8-9
5	5	-	2	-	3	-	4	-	-	-	1-3-5-7
6	-	5	-	2	4	-	-	3	-	-	2-4-5-8
7	4	-	-	3	-	-	-	-	-	2	1-4-10
8	-	-	5	-	2	4	-	-	3	-	3-5-6-9
9	-	-	3	-	-	-	5	-	2	4	3-7-9-10
10	-	-	-	5	-	2	4	-	-	3	4-6-7-10

Comments: Blade Size #15

Performed By/Date: 02-20-14

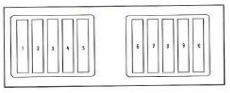
Reviewed By/Date: 02/20/14

Figure 15

Run #2 Documentation

Vision System Verification

The number inside the matrix (2-5) represents the kinds of defects that the vision system can detect.
- 2 = Crack Blade
- 3 = Improper Small Heat Stake
- 4 = Improper Large Heat Stake
- 5 = Test Aborted (no blade)



Representation of nest positions at machine

Machine Index	Nest Number 1	2	3	4	5	6	7	8	9	10	Rejected Nest by Vision System
11	2	-	-	-	3	-	-	-	-	-	1-5
12	-	4	-	-	-	-	-	-	5	-	2-9

Comments: Blade Size #15

Performed By/Date: 02-20-14

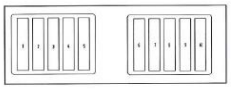
Reviewed By/Date: 02/20/14

Figure 16

Run #2 Documentation Cont.

Vision System Verification

The number inside the matrix (2-5) represents the kinds of defects that the vision system can detect.
- 2 = Crack Blade
- 3 = Improper Small Heat Stake
- 4 = Improper Large Heat Stake
- 5 = Missing Blades



Representation of nest positions at machine

Machine Index	Nest Number 1	2	3	4	5	6	7	8	9	10	Rejected Nest by Vision System
1	-	4	-	-	3	-	-	-	5	-	2-5-9
2	3	-	-	-	5	-	2	4	-	-	1-5-7-8
3	-	2	-	-	-	-	-	-	-	5	2-10
4	-	3	-	-	-	5	-	2	4	-	2-6-8-9
5	5	-	2	-	3	-	4	-	-	-	1-3-5-7
6	-	5	-	2	4	-	-	3	-	-	2-4-5-8
7	4	-	-	3	-	-	-	-	-	2	1-4-10
8	-	-	5	-	2	4	-	-	3	-	3-5-6-9
9	-	-	3	-	-	-	5	-	2	4	3-7-9-10
10	-	-	-	5	-	2	4	-	-	3	4-6-7-10

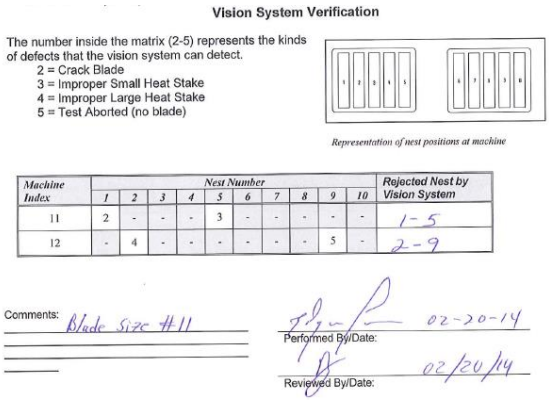
Comments: Blade Size #11

Performed By/Date: 02-20-14

Reviewed By/Date: 02/20/14

Figure 17

Run #3 Documentation



Vision System Verification

The number inside the matrix (2-5) represents the kinds of defects that the vision system can detect.
2 = Crack Blade
3 = Improper Small Heat Stake
4 = Improper Large Heat Stake
5 = Test Aborted (no blade)

Representation of nest positions at machine

Machine Index	Nest Number										Rejected Nest by Vision System
	1	2	3	4	5	6	7	8	9	10	
11	2	-	-	-	3	-	-	-	-	-	1-5
12	-	4	-	-	-	-	-	-	5	-	2-9

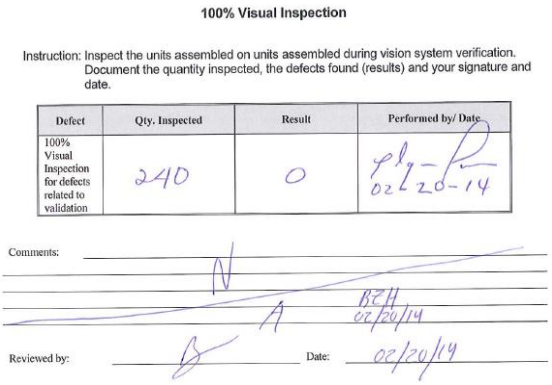
Comments: Blade Size #11

Performed By/Date: 02-20-14

Reviewed By/Date: 02/20/14

Figure 18
Run #3 Documentation Cont.

Visual Inspections



100% Visual Inspection

Instruction: Inspect the units assembled on units assembled during vision system verification. Document the quantity inspected, the defects found (results) and your signature and date.

Defect	Qty. Inspected	Result	Performed by/ Date
100% Visual Inspection for defects related to validation	240	0	02-20-14

Comments: N A BZH 02/20/14

Reviewed by: Date: 02/20/14

Figure19
Post PQ Visual Inspections

MSA results for each of the three (3) runs were perfect, with the visual system rejecting all defects and passing all the good parts. Also, the visual inspection performed after PQ completion have cero (0) observed defects.

CONCLUSION

This Installation, Operation, and Performance Qualification (IOPQ-14-003) were executed with acceptable results. Every Challenge in this Installation, Operation, and Performance Qualification was documented on its respective appendix. Test results indicate that the new Cognex vision system, installed by DAP advance automation, complies with the actual requirements for visual inspections on PDS machine. During OQ, an MSA was executed with acceptable results, allowing us to confirm that the new Cognex vision system is capable to inspect all applicable defects. MSA results were documented on attachment #8. Samples were taken from PQ runs for visual inspection of broken blade (920 units), non-conforming heat stake (354 units), and missing blade (354 units). All of them had 0 observed defects, as documented on the validation report, allowing us to confirm that the new Cognex vision system is capable to inspect all defects.

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