Complaint Number: 100163

Report 8D

Generated By: Seb Houle
Generated On: 21 Jun 2011

I. COMPLAINT INFORMATION

Origination Date	17 May 2011		
Sales Name	Kim McLaughlin	Sales Office	Windsor
Telephone	-	Fax Number	-
Email	kim.mclaughlin@scapa.com		
Customer Complaint Ref			
Customer Name	Covidien- Nellcor		
SAP Customer Number	126673	Customer Order N°	
Customer Part Number			

1) Invoices And Items On Complaint

(a) SAP Invoice Number	9700036618	Invoice Date	17 Mar 2011
- Material	158060	Batch	
Material Description	>063678A DWG #063678 REV A		
- Material	158060	Batch	ING0007745
Material Description	>063678A DWG #063678 REV A		
(b) SAP Invoice Number	9700037182	Invoice Date	31 Mar 2011
- Material	158060	Batch	
Material Description	>063678A DWG #063678 REV A		
- Material	158060	Batch	ING0008213
Material Description	>063678A DWG #063678 REV A		

- Material	158060	Batch	ING0007922
	Material Description		
	>063678A DWG #063678 REV A		
(c) SAP Invoice Number	9700037325	Invoice Date	04 Apr 2011
- Material	158060	Batch	
	Material Description		
	>063678A DWG #063678 REV A		
- Material	158060	Batch	0000574208
	Material Description		
	>063678A DWG #063678 REV A		
- Material	158060	Batch	ING0008210
	Material Description		
	>063678A DWG #063678 REV A		
(d) SAP Invoice Number	9700037722	Invoice Date	14 Apr 2011
- Material	158060	Batch	
	Material Description		
	>063678A DWG #063678 REV A		
- Material	158060	Batch	ING0008597
	Material Description		
	>063678A DWG #063678 REV A		

2) Problem Description

Another customer complaint for the adhesive voids on the RX715/10.0 linked to another complaint 18439.

per customer: "Our production supervisors reported us some issues with PN 063678 & PN 10032964; they detected voids of adhesive under the top"

PN 063678□ □
Lots:
ING0008210□ WIN0017250 1400 ea□ □
0000574208□ WIN0017250 180 ea
ING0008213□ WIN0017250 700 ea
ING0008284□ WIN0019354 700 ea
ING0008597□ WIN0019363 700 ea

Total Qtty: 3680 units segregated

PN 10032964

Lots:

0000309587 (I00032009D old batch before SAP) "2000 ea will not be credited back"

ING0007922 WIN0014530 1000 ea

ING0007745 WIN0014620 1000 ea

Total Qtty: 4000 units segregated (2000 ea cannot be credited back beacuse they are older than 1 year)

Actions Requested From The Customer

RMA# to return the parts and credit

3) Containment Actions

Checked inventory and no parts from the same batches were in stock from the batches that the customer complained about.

II. EVALUATION AND ACTION

Sample/photo Received	No				
Date					
Process Owner	Seb Houle				
Team Leader	shoule				
Is Complaint Valid?	Yes	Return The Goods	No	Dispose The Goods	Yes

Comments

1) Analysis

Although no samples were received, this complaint is indicative of an ungoing/repeat issue (Ref: Complaint# 18439), in which the long-term corrective actions have not yet been implemented. The root cause of the issue is adhesive voids during the production, which result from the manual operation of the adhesive level. While short-term corrective action has been implemented until the implementation of long-term corrective action, there was some inventory inprocess prior to the implementation of the short-term corrective action.

Summary of Complaint #18439
Analysis: The samples returned to Scapa clearly show that there is low adhesive coat weight present. Measures have been put in place to prevent “start-up” or “void-out” material from making its way into the final product so something must have taken place during the coating run.

Author	Seb Houle	Date	20 Jun 2011

2) Root Causes

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Summary of Complaint #18439
Root causes: Batch notes from this coating run show that the adhesive trough ran low, causing low adhesive coat weights during this run. The material was flagged at the time the low weights were identified and then again once the weights were brought back into specification. On the coater (#1) that this material runs, the adhesive level in the adhesive trough is monitored manually by the “wet end” operator. (This material must be run on coater #1 since it requires tension controls that are exclusive to this coater). This is a part of the process that relies on the operator keeping an eye on the adhesive level.

During the converting process the slitting operator culled out material from the 1st flag to the 2nd, believing that he removed all of the low weight material. Unfortunately there was still low weight material past the flag that should also have been removed.

The slitting operators did not know to peel back the release liner to inspect the adhesive coverage.

Author	Seb Houle	Date	20 Jun 2011

3) Possible Solutions

Author		Date	

4) Implemented Perm Corrective Actions

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Summary of Complaint #18439
Containment Actions: QA has reviewed this complaint with the machine operators that ran both the coating and slitting portions of this job.
Possible Solutions: QA has reviewed this complaint with the machine operators that ran this job. Notes have been added to the engineering routings stressing the importance of keeping a close eye on the adhesive level. There is also a note regarding the importance of detailed coating batch notes. In this case it would have been beneficial to explain that the defect went further than the void flags.
Scapa Engineering is going to research what types of level sensors are available that would fit on this particular coater. Additionally, another coater is being upgraded to allow for the degree of tension control that is necessary to allow for this material to be run on it. Upon competition of these modifications this material can be moved to this other coater (#3). This upgrades are projected to be completed the first week of August 2011. (SH -6/20/11)
The complaint was also reviewed with the converting department. It was explained to the converting operators that they must run past the 2nd flag when removing “void-outs”. The liner must be pulled back to confirm that there is good adhesive coverage before splicing the material together. A note to that affect was added to the slitting specification.
Implemented perm corrective actions: QA has reviewed this complaint with the machine operators that run this job. Notes have been added to the engineering routings stressing the importance of keeping a close eye on the adhesive level in the trough. There is also a note regarding the importance of clear coating batch notes so that the slitting operator has a clear understanding of what and where the defect is. In this case it would have been beneficial to the slitting operator if the batch notes explained that the defect went further than the void flags.
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How was the Implemented Permanent Corrective Action Validated: Engineering has sourced a sensor and is currently investigating the best possible way of mounting it to the coating head. This will not be easy due to the high possibility of the sensors being damaged by the cleaning solvents and the adhesives we coat.
Preventive Action: Engineering is in the process of investigating level sensors for coating head so we are not relying fully on the operator.
Visual aids have been photographed and will be available to the operators so that they have a clear understanding of what an acceptable adhesive converge looks like.

Author	Seb Houle	Date	20 Jun 2011
Estimated Date		Implementation Date	
Validation Date			

5) Corrective Actions Validation

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6) Preventive Actions

Author		Date	
Estimated Date		Implementation Date	
Validation Date			

7) Review Of Documentation

(a) MSR

Reviewed?	No		
Reference		Date	

(b) Flow chart, control plan, work inspection instructions

Reviewed?	No		
Reference		Date	

(c) FMEA

Reviewed?	No		
Reference		Date	

(d) Customer specification

Reviewed?	No		
Reference		Date	

8) Congratulate The Team