

AM Full, SN Full



## Customer Complaint and Non Conformance Review Screen

[Show All Generic Issues](#)  
[Show All Viamed Issues](#)  
[Show All Vandagraph Issues](#)  
[Show All VST Issues](#)  
[Show All Human Med Issues](#)  
[Show All Viamed Properties Issues](#)  
[Show All The Pointless Logo Company Issues](#)  
[Show All Non Minor Issues](#)

## To Filter to Company Issues you need to tag any in the Genetic Issues first

Unreviewed Telephone Complaints

Audit Organisation and Process Verification Internal Process Verification									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
<a href="#">317929</a> <a href="#">17 Jan 2024</a>	Email Distribution (366)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the global mailbox, there should be no mails more than a Day old. Give allowance for Monday mornings, there should be no emails older than Friday afternoon. Also note size of space used in Global inbox

**17 Jan 2024 Derek Lamb**

Done

### Non Conformance Issues

[Viamed](#) [Vandagraph](#) [VST](#) [Human Med](#) [Viamed Properties](#) [The Pointless Logo Company](#)

		Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">317342</a> 10 Jan 2024	Shipped Items Return to Supplier BOX954	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX954 warrant a NON conformance report via the CAPA process VM3COP10

**10 Jan 2024 Derek Lamb**

viamed maxtec sensor normal fail type

		Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">316859</a> 05 Jan 2024	Non conformance review history VST (285)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors.

Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 09 Jan 2024 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st Jan 23. Nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. Non Conformance issues review screen - No issues. No other feedback issues relating to non conformances that need to be monitored or reviewed. Non conformance meeting header - Nothing in last month. Nothing further. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

### 09 Jan 2024 Derek Lamb

Done

### Audit Picking and Packing

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">316318</a> <a href="#">01 Jan 2024</a>	Audit 01 Picking Packing VST (194)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 01 due BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 08 Jan 2024 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Completed audit attached no issues please review

### 09 Jan 2024 Derek Lamb

thankyou

## Audit Design Control

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">316317</a> <a href="#">01 Jan 2024</a>	Audit 03 Design Control VST (193)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

System Generated Audit 03 NOTE DESIGN REMOVED FROM VST, AUDIT NOT REQUIRED. LEFT IN FOR FUTURE USE Review Last years Audit see if its still suitable Before Proceeding you need to update the Processes attached to the Audit Search the Document in the Index, View the Admin Page Copy and Paste the Attached Processes, replacing them in the current audit Any non Conformances from the Audit: Create a follow up / related Issue, With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution if its a major / critical non conformance complete form QC 18

## Audit Internal Audits

[Viamed](#) [Vandagraph](#) [VST](#) [Human Med](#) [Viamed Properties](#) [The Pointless Logo Company](#)

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">316128</a> <a href="#">28 Dec 2023</a> 313880	Audit 17 Internal Audits VST (191)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Task 1094 not completed							
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Derek Lamb

Added by Helen Lamb sent to Derek Lamb

Audit 17 Internal Audits VST (191) Task 1094 not completed Board meeting has been delayed as a Director has been really unwell. Will be carried out in January 24

## Non Conformance Issues

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
314196 05 Dec 2023	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

## 14 Dec 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st Dec 23. Nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. Non Conformance issues review screen - No issues. No other feedback issues relating to non conformances that need to be monitored or reviewed. Non conformance meeting header - Nothing in last month. Nothing further. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

## 15 Dec 2023 Derek Lamb

thankyou

Audit of Audits  
VST

Issue / Primary	Subject/Notes	Minor Internal Error i.e. not ISO	Reviewed Non Conformity	Determined Cause of Non	Evaluated action to Ensure	Planning and documenting action needed	Verify Action does not adversely	Effectiveness of corrective
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ID / Call ID	Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	/ Complaint and determine if its a vigilance Issue requiring a corrective action plan	Conformity / Complaint	does not recur	and implementation QC 28b	affect Safety	Performance or regulatory requirements	action reviewed
313881 01 Dec 2023	Audit 21 Audit Of Audit VST (192)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 21 due Review the Audit Calendar Screen ISO -> Audit Calendar Complete Audit 21 Confirm if Audit calendar needs changing. BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**29 Dec 2023 Derek Lamb**

Next Action Changed From Derek Lamb To Helen Lamb ive given you the audit to scan and attach to this issue please

**02 Jan 2024 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Completed audit attached, completed by you. no issues please check correct is attached.

**02 Jan 2024 Derek Lamb**

Audit Internal Audits

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety	Effectiveness of corrective action reviewed
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		Non conformance / or dealt with in s						
313880 01 Dec 2023	Audit 17 Internal Audits VST (191)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 17 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 28 Dec 2023 Helen Lamb

Created Related Issue #316128

Added by Helen Lamb sent to Derek Lamb

Audit 17 Internal Audits VST (191) Task 1094 not completed Board meeting has been delayed as a Director has been really unwell. Will be carried out in January 24

### 28 Dec 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Audit completed issue 316128 sent re task not completed. Please review the attached.

### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
313647 28 Nov 2023	Shipped Items Return to Supplier BOX941	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX941 warrant a NON conformance report via the CAPA process VM3COP10

### 28 Nov 2023 Derek Lamb

80100082240983M01112018No Output vst normal sensor type fail no capa required

### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">311635</a> <a href="#">06 Nov 2023</a>	Non-Conformance Vandgraph Website	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

Added by Derek Lamb sent to Helen Lamb

See Main Issue

**09 Nov 2023 Helen Lamb**

have spoken to Mike and advised him these need to be carried out more regularly

**Non Conformance Issues**

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">311536</a> <a href="#">06 Nov 2023</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and

non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 15 Nov 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st Nov 23. Nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. Non Conformance issues review screen - No issues. No other feedback issues relating to non conformances that need to be monitored or reviewed. Non conformance meeting header - Nothing in last month. Nothing further. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

### 16 Nov 2023 Derek Lamb

Done

### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">311426</a> <a href="#">03 Nov 2023</a>	Non-Conformance Vandgraph Website	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Catrin Hird sent to Derek Lamb

INFORMATION ONLY ISSUE **DO NOT ADD NOTES!**

Order have not been marked as fulfilled from 18th October for 13 Vandagraph orders. I will go through them now to check system and fulfil.

### 06 Nov 2023 Derek Lamb

Created Related Issue #311635

Added by Derek Lamb sent to Helen Lamb

See Main Issue

### Audit Organisation and Process Verification VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">311116</a> <a href="#">01 Nov 2023</a>	Audit 20 Process Verification To Management VST (181)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 20 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**05 Dec 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Completed audit attached no outstanding issues. Please review

**05 Dec 2023 Derek Lamb**

thankyou

#### BSI Minor Non conformances

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		conformance / or dealt with in s						
311074 31 Oct 2023	BSI 2391793-202310-N1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

Added by Derek Lamb sent to Derek Lamb

Servicing process was not fully effective as servicing procedure and information was not seen to include analysis to determine if information is to be handled as a complaint. Clause 7.5.4 VOP09, 24. 11. 2021 Repairs and Servicing SRN 36055, Tom Thumb SN 0401370, 11. 10. 2023 SRN 36045, barcode 987618, M000SN 4278, Microstim DB3, Report 1697639395, 18.10. 2023

**31 Oct 2023 Derek Lamb**

Next Action Changed From Derek Lamb To Helen Lamb

**02 Nov 2023 Helen Lamb**

Priority Changed From 5 To 1

**03 Nov 2023 Helen Lamb**

next version to review

**06 Nov 2023 Derek Lamb** report sent to BSI today Mostafa.Seddighi@bsigroup.com>, RSCAPS@bsigroup.com

Audit Management Review

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
309399 16 Oct 2023	Audit 18 Management Review VST (188)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 18 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**15 Nov 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Completed Audit Attached please review. Assessed from the 2022 Management review, 2023 is now due and planned for next month. Nothing outstanding

**15 Nov 2023 Helen Lamb**

i labelled the attached doc wrong its for 2023

**16 Nov 2023 Derek Lamb**

Done

**16 Nov 2023 Derek Lamb**

Done

Complaints from VST to a Supplier

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
309020 10 Oct 2023	test	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Derek Lamb sent to Derek Lamb

test

**11 Oct 2023 Derek Lamb**

Done

Future Reviews - Internal Audits

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		Failure but no requirement to Escalate Non conformance / or dealt with in s						
308987 10 Oct 2023	Objective Ensure the Audits are performed within a timely manner Review the Tasks and Audits for the Audits Should be no more than 1 outstanding issue for each section	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

General  
10 Oct 2023 Derek Lamb  
on going

VST Customer Complaints  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
308961 10 Oct 2023	test	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
10 Oct 2023 Derek Lamb  
test issue

**11 Oct 2023 Derek Lamb**  
Done

Non Conformance Issues

## VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">308534</a> <a href="#">05 Oct 2023</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Helen Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

**05 Oct 2023 Helen Lamb**

Please see issue 305778. September issue was done late due to illness, so covers Octobers Non conformance review.

**05 Oct 2023 Helen Lamb**

Please see issue 305778. September issue was done late due to illness, so covers Octobers Non conformance review.

## Non Conformance Issues

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		Non conformance / or dealt with in s						
307437 22 Sep 2023	Shipped Items Return to Supplier BOX938	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX938 warrant a NON conformance report via the CAPA process VM3COP10

**27 Sep 2023 Derek Lamb**

vst o2 sensor unstable output, SN aware, normal fail type, no cap required at this time

## VIAMED Customer Complaints

Viamed

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
306816 15 Sep 2023 306804	Feedback for initial order - Damaged Parcels Non Conformance	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Steve Hardaker

Added by Derek Lamb sent to Derek Lamb  
this needs further investigation**15 Sep 2023 Derek Lamb**Header Changed From 238 Non Conformance Issues Non Conformance Issues To VIAMED Customer Complaints  
VIAMED Customer Complaints**15 Sep 2023 Derek Lamb**

Next Action Changed From Derek Lamb To Steve Hardaker can you open a CCR, reference number, Its a shipping/packaging issue, so no mhra / bsi notifications are required.

**15 Sep 2023 Derek Lamb**

I believed we were shipping the items in teh same manner the supplier ships to us, I asked robert to photograph the latest shipment from maxtec to us, fortunatly then have sent a shipment this week, and believe it or not see attached photos

**15 Sep 2023 Derek Lamb**

Created Related Issue #306817

Added by Derek Lamb sent to Steve Nixon

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Steve, Looks like we need to inform maxtec of the shipping method and state of the boxes actually delivered, We've opened an internal customer complaint, see Issue 306816

**15 Sep 2023 Steve Hardaker**

**15 Sep 2023 Steve Hardaker**

Requires CCR number. Check file on Monday.

**25 Sep 2023 Steve Hardaker**

Opened CCR156 and documented so far.

**18 Oct 2023 Steve Hardaker**

SN recommendations for corrective actions: 1) Large plastic bags to encase the contents have been ordered. 2) Packing tape will be applied fully around each box. 3) Large external Viamed labels will be applied, to assist in identification. 4) We will try and evaluate vertical strengthening piers applied in each of the box corners. 5) The double walled boxes that we use are deemed suitable. 6) Packing procedures will be generated/edited. Documented as far as can be done for now. You may want to consider this now closable, or wait until further shipments are sent and ask Ryan to follow up on the efficacy of corrective actions. See paper complaint file the the CCR report, which needs signing off by a Director.

#### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">305816</a> <a href="#">05 Sep 2023</a>	Shipped Items Return to Supplier BOX930	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX930 warrant a NON conformance report via the CAPA process VM3COP10

**05 Sep 2023 Derek Lamb**

VST normal sensor fail type Done

#### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance	Reviewed Non Conformity / Complaint	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and	Verify Action does not adversely affect Safety Performance	Effectiveness of corrective action reviewed
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		or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	and determine if its a vigilance Issue requiring a corrective action plan		implementation QC 28b	or regulatory requirements
<a href="#">305778</a> <a href="#">05 Sep 2023</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 03 Oct 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st Oct 23. I have had Covid so this has been delayed this will cover the next issue too. So August and September 23. Nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. Non Conformance issues review screen - No issues. No other feedback issues relating to non conformances that need to be monitored or reviewed. Non conformance meeting header - Nothing in last two months. Nothing further. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

### 04 Oct 2023 Derek Lamb

thankyou

Audit Purchasing  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		to Escalate Non conformance / or dealt with in s							
305390 01 Sep 2023	Audit 05 Purchasing Suppliers VST (190)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 05 BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**12 Sep 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Completed audit attached no issues please review

**15 Sep 2023 Derek Lamb**

thankyou

Audit Contract Review  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
305388 01 Sep 2023	Audit 02 Contract Review VST (187)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 02 Review Last years Audit see if its still suitable Before Proceeding you need to update the Processes attached to the Audit Search the Document in the Index, View the Admin Page Copy and Paste the Attached Processes, replacing them in the current audit Any non Conformances from the Audit: Create a follow up / related Issue, With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution if its a major / critical non conformance complete form QC 18

**11 Sep 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Audit completed and no issues please review the attached.

**11 Sep 2023 Derek Lamb**

thankyou

## VIAMED Customer Complaints

Viamed

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
304005 15 Aug 2023	4420826 report of gas leakage	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Steve Hardaker

Added by Steve Nixon sent to Steve Hardaker

As discussed, please treat as a customer complaint. When we have further information we can then decide if it warrants processing as a complaint to Bluepoint. Shipped via Trionara, but being used by Saadat. 100 boxes of 4420826 shipped 17-04-2023 RVM141219-1 4 boxes 4420823 shipped 21-11-2022 RVM140395-1 4 boxes 4420826 shipped 21-11-2022 RVM140395-1

**16 Aug 2023 Steve Hardaker**

Opened customer complaint report CCR155.

## Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		/ or dealt with in s							
303194 07 Aug 2023	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>						

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

#### 07 Aug 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st July 23. Nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. Non Conformance issues review screen - No issues. No other feedback issues relating to non conformances that need to be monitored or reviewed. Non conformance meeting header - 300731 issue wrong invoice sent to customer, human error, relevant staff have been spoken to. Nothing further. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

#### 07 Aug 2023 Derek Lamb

thankyou

Audit Health and Safety VST									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
302436 01 Aug 2023	Audit 19 Health And Safety VST (186)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Do HSE Audit Audit No 19 Review Last years Audit see if its still suitable BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for

Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 01 Aug 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Completed audit attached, please review. No outstanding issues.

### 02 Aug 2023 Derek Lamb

Thankyou Done

### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">301436</a> <a href="#">19 Jul 2023</a> 299479	Audit 11 Repairs And Service VST (179) Non Conformance QA records	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Helen Lamb sent to Derek Lamb

Test records have QA but not in the QA Data base. system to be updated

### 21 Jul 2023 Derek Lamb

Linked TaskID Changed From 0 To 456

### 18 Sep 2023 Derek Lamb

updated the stock references to have a pass fail and output giefs to appear in the SRS system.

### Audit Analysis of Data

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective	Reviewed Non Conformity / Complaint and determine if its a vigilance	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Issue requiring a corrective action plan						
300839 13 Jul 2023	Audit 23 Analysis Of Data VST (185)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 23 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 31 Jul 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Completed audit attached. Please check, the only issue outstanding is the one for the management review which cannot be completed until signing off in the next meeting.

### 31 Jul 2023 Helen Lamb

### 31 Jul 2023 Derek Lamb

thankyou

### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
300820 12 Jul 2023 300732	Order Error : 143286 New Error	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

Added by Helen Lamb sent to Helen Lamb

Incorrect invoice sent to customer, sent invoice for M3S RST142896-1 instead of RST143286-1. We have sent the wrong invoice to a VST customer. Please be extra careful when adding invoices to your emails. Especially VST ones.

08 Aug 2023 Helen Lamb

08 Aug 2023 Helen Lamb

Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
300732	Order Error : 12 Jul 2023	143286 New Error	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

Auto Issue from Error Log 143286

Order Entered by Janine Gill

Order Checked by Kate Griffiths

Office

Error was New Error

Fault:

Incorrect invoice sent to customer, sent invoice for M3S RST142896-1 instead of RST143286-1. Non-Conformance raised issue #300731

Possible Fix

12 Jul 2023 Helen Lamb

Created Related Issue #300820

Added by Helen Lamb sent to Helen Lamb

Incorrect invoice sent to customer, sent invoice for M3S RST142896-1 instead of RST143286-1. We have sent the wrong invoice to a VST customer. Please be extra careful when adding invoices to your emails. Especially VST ones.

Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non	Reviewed Non Conformity /	Determined Cause of Non	Evaluated action to Ensure	Planning and documenting action needed and	Verify Action does not adversely affect Safety	Effectiveness of corrective action reviewed

		Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Complaint and determine if its a vigilance Issue requiring a corrective action plan	Conformity / Complaint	does not recur	Implementation QC 28b	Performance or regulatory requirements
300731 12 Jul 2023	rEvo x M3S Incorrect Invoice Sent to Customer	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Catrin Hird sent to Derek Lamb

Incorrect invoice sent to customer, sent invoice for M3S RST142896-1 instead of RST143286-1 for rEvo. Also raised as Log Error against rEvo order.

**07 Aug 2023 Derek Lamb**

first ever occurrence of this - looks like human error, spoken to office staff no further action taken

### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
299811 05 Jul 2023	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month

since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 10 Jul 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st June 23. Nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to non conformances that need to be monitored or reviewed. Non conformance meeting header - nothing new Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

### 11 Jul 2023 Derek Lamb

Done

### Audit Repairs and Service VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">299479</a> <a href="#">03 Jul 2023</a>	Audit 11 Repairs And Service VST (179)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 11 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 19 Jul 2023 Helen Lamb

Created Related Issue #301436

Added by Helen Lamb sent to Derek Lamb

Test records have QA but not in the QA Data base. system to be updated

### 10 Aug 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb completed audit attached, no issues

### 25 Aug 2023 Derek Lamb

thankyou

Audit Training VST									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
299315 30 Jun 2023	Audit 08 Training VST (184)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Derek Lamb

System Generated Audit 08 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**21 Jul 2023 Derek Lamb**

Next Action Changed From Derek Lamb To Helen Lamb

**24 Jul 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb completed audit attached that you carried out. Please check it scanned ok

**24 Jul 2023 Derek Lamb**

Done

Non Conformance Issues  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested /	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		Product Failure but no requirement to Escalate Non conformance / or dealt with in s							
299310 29 Jun 2023	Shipped Items Return to Supplier BOX921	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX921 warrant a NON conformance report via the CAPA process VM3COP10

**29 Jun 2023 Derek Lamb**

reviewed vst , normal fail types

**29 Jun 2023 Derek Lamb**

reviewed vst , normal fail types

## Audit Documentation Control

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
297581 12 Jun 2023	Audit 10 Documentation Control Viamed (27)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated BSI Audits Calendar BSI Audit Documentation Control Audit 10. BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**26 Jun 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb audit done no issues

**26 Jun 2023 Derek Lamb**

thankyou

**Non Conformance Issues**

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">296962</a> <a href="#">05 Jun 2023</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

**09 Jun 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st May 23. Issue 295394 QC21 forms generated for BSI minors, not a problem and nothing else of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to non conformances that need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

**13 Jun 2023 Derek Lamb**

Done

**VST Customer Complaints**

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative	Reviewed Non Conformity / Complaint and determine if its a	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	vigilance Issue requiring a corrective action plan						
296752 01 Jun 2023	Divesoft - complaint list number 23OB0251	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Steve Nixon sent to Steve Hardaker

Concerns 8010020 oxygen sensors Please process through the updated complaints system. See the attached emails. I will get back to Divesoft with a summary of the findings concerning the overspill of the conformal coating and also process the credits relating to the SRS.

**02 Jun 2023 Steve Nixon**

Credit done TST143790-0

**02 Jun 2023 Steve Hardaker**

There are no attached emails, please can you upload them and bounce this issue back to me.

**22 Jun 2023 Derek Lamb**

Linked TaskID Changed From 0 To 1193

**14 Aug 2023 Steve Hardaker**

Customer Complain Report CCR154 was been generated. Just need to print along with supporting documents and add to the paper file.

**16 Aug 2023 Steve Hardaker**

Next Action Changed From Steve Hardaker To Derek Lamb Added to paper file in office meeting room. I believe this is now complete, just requires signing off by a Director.

**23 Aug 2023 Derek Lamb**

Done

Audit Calibration  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		requirement to Escalate Non conformance / or dealt with in s							
295678 22 May 2023	Audit 06 Calibration VST (182)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 06 BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**23 Jun 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb completed Audit attached no issues

**26 Jun 2023 Derek Lamb**

thankyou

#### Non Conformities Review

Viamed Vandagraph VST Human Med Viamed Properties The Pointless Logo Company

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
295327 16 May 2023	2342435-202305-N2 ISO 9001:2015 9.2 Minor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

Added by Derek Lamb sent to Derek Lamb

1. The unique identifier (from the BSI report and also any internal reference). 2. The statement of Nonconformity as written in the BSI report. 3. Root Cause Analysis. 4. Relevant Immediate Correction (where applicable). 5. Relevant and Proportionate Corrective Action. 6. Person responsible to complete the action(s). 7. Time for completion of all identified actions. The process for internal audit is not fully effective as it was not clear that all issues raised during internal audit were part of the non- conformance review process as per documented procedure 9.2 Internal audit Picking packing audit 2023

**16 May 2023 Derek Lamb**

Next Action Changed From Derek Lamb To Helen Lamb

**18 May 2023 Helen Lamb**

HL revision added 295327.12614 qc 21 initial document N2\_18\_05\_23 HL1

## Non Conformities Review

Viamed	Vandagraph	VST	Human Med	Viamed Properties	The Pointless Logo Company				
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
295321 16 May 2023	2342435-202305-N1 ISO 9001:2015 5.2 Minor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

Added by Derek Lamb sent to Derek Lamb

1. The unique identifier (from the BSI report and also any internal reference). 2. The statement of Nonconformity as written in the BSI report. 3. Root Cause Analysis. 4. Relevant Immediate Correction (where applicable). 5. Relevant and Proportionate Corrective Action. 6. Person responsible to complete the action(s). 7. Time for completion of all identified actions. The process for the quality policy is not fully effective as it was defined as a secondary level document. 22062 VM3COP.00.00 Company quality policy 16 sept 2017

**16 May 2023 Derek Lamb**

Next Action Changed From Derek Lamb To Helen Lamb

**18 May 2023 Helen Lamb**

section 5.2 of 9001 first revision by me doc named 295321.12613 qc21 initial document N1\_18\_05\_23 HL1

## Non Conformance Issues

Viamed	Vandagraph	VST	Human Med	Viamed Properties	The Pointless Logo Company				
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested /	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	

		Product Failure but no requirement to Escalate Non conformance / or dealt with in s							
295019 12 May 2023	Shipped Items Return to Supplier BOX915	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX915 warrant a NON conformance report via the CAPA process VM3COP10

**15 May 2023 Derek Lamb**

normal sensor type fails

### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
294268 05 May 2023	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

**15 May 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st April 23 nothing of concern or to be investigated or reported on. BSI were in last week for 9001:2015 and four Minors were given, these will be investigated and processed shortly. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to

non conformances that need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

### 15 May 2023 Derek Lamb

thankyou

### Audit Post Marketing Surveillance

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
293724 02 May 2023	Audit 22 Post Market Surveillance VST (180)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 22 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 02 Jun 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb completed audit attached, no issues from this VST audit

### 05 Jun 2023 Derek Lamb

thankyou

### Audit Production

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	action plan						
293720 02 May 2023	Audit 15 Production VST (175)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 15 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 02 Jun 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb completed audit attached , no issues and no production carried out by VST

### 02 Jun 2023 Derek Lamb

thankyou

### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
292702 18 Apr 2023	Shipped Items Return to Supplier BOX912	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX912 warrant a NON conformance report via the CAPA process VM3COP10

### 28 Apr 2023 Derek Lamb

Done

Audit Handling and Storage VST									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
<a href="#">292443</a> <a href="#">17 Apr 2023</a>	Audit 07 Handling And Storage VST (178)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Derek Lamb

System Generated Audit 07 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**19 Jun 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb audit completed no issues please review Done

**19 Jun 2023 Derek Lamb**

thankyou

Non Conformance Issues VST									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	

		to Escalate Non conformance / or dealt with in s							
291403 05 Apr 2023	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 03 May 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st March 23 nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to non conformances that need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

### 09 May 2023 Derek Lamb

thankyou

Audit CE Files  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
290136 22 Mar 2023	Audit 12 CE Files VST (176)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 12 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all

of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 29 Mar 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Scanned to issue completed by Steve Nixon and Derek Lamb. Attached.

### 30 Mar 2023 Derek Lamb

thankyou

### 14 Sep 2023 Derek Lamb

Audit Goods Inwards and Product Identity  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">288861</a> 09 Mar 2023	Audit 09 Goods Inward And Product Identity VST (174)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 09 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 13 Apr 2023 Helen Lamb

Created Related Issue #292109

Added by Helen Lamb sent to Derek Lamb

there are two SRSs without email addresses All the other info is there but i though this should probably be in here too. I am unsure if this is a system thing not pulling it in or a person thing

### 13 Apr 2023 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb completed audit attached one issue 292109 re SRS info.

### 18 Apr 2023 Derek Lamb

thankyou

Non Conformance Issues VST									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
<a href="#">288494</a> <a href="#">06 Mar 2023</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

**22 Mar 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st February 23 nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to non conformances that need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

**23 Mar 2023 Derek Lamb**

thankyou

Non Conformance Issues  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	corrective action plan					
284669 25 Jan 2023 246776	Audit 01 Picking Packing VST (194) Needs a re write as system been updated	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

Added by Helen Lamb sent to Helen Lamb

Both Viamed and VSt need a re write as reflects old system

**17 Feb 2023 Helen Lamb**

Priority Changed From 5 To 1

**11 May 2023 Derek Lamb**

Header Changed From 614 VST Audits Calander Audit Picking and Packing To VST Management Non Conformance Issues

**26 Jun 2023 Helen Lamb**

Done

**26 Jun 2023 Helen Lamb**Audit Picking and Packing  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

281965 03 Jan 2023	Audit 01 Picking Packing VST (194)	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
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Derek Lamb

System Generated Audit 01 due BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**16 Feb 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb no issues, Audit attached please review

**20 Feb 2023 Derek Lamb**

reviewed

Audit Design Control  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
281964 03 Jan 2023	Audit 03 Design Control VST (193)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 03 NOTE DESIGN REMOVED FROM VST, AUDIT NOT REQUIRED. LEFT IN FOR FUTURE USE Review Last years Audit see if its still suitable Before Proceeding you need to update the Processes attached to the Audit Search the Document in the Index, View the Admin Page Copy and Paste the Attached Processes, replacing them in the current audit Any non Conformances from the Audit: Create a follow up / related Issue, With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution if its a major / critical non conformance complete form QC 18

**23 Jun 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb you were going to go through this with Steve

**20 Sep 2023 Derek Lamb**

Next Action Changed From Derek Lamb To Helen Lamb

**21 Sep 2023 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb completed audit attached please can you check its ok . no issues

### 22 Sep 2023 Derek Lamb

THANKYOU

### Audit of Audits

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">279306</a> <a href="#">01 Dec 2022</a>	Audit 21 Audit Of Audit VST (192)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

System Generated Audit 21 due Review the Audit Calendar Screen ISO -> Audit Calendar Complete Audit 21 Confirm if Audit calendar needs changing. BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 06 Dec 2022 Helen Lamb

Scanned Audit attached as per your request.

### 06 Dec 2022 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb please review and complete

### 06 Dec 2022 Helen Lamb

Reviewed ok no issues

### Audit Internal Audits

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective	Reviewed Non Conformity / Complaint and determine if its a vigilance	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Issue requiring a corrective action plan						
279305 01 Dec 2022	Audit 17 Internal Audits VST (191)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 17 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

#### 06 Dec 2022 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb audit completed and reviewed, Was carried out by both of us, no issues

#### 06 Dec 2022 Derek Lamb

reviewed thankyou

#### Non Conformance Issues

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
273702 05 Oct 2022	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors.

Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 28 Oct 2022 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues (not automatically generated) to 1st September 22 nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to non conformances that need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above #276042 issue sent re Customer Complaint and Non Conformance Review Screen as not filtering to VST

### 31 Oct 2022 Derek Lamb

ok, will fix filter on the page

### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
270891 05 Sep 2022	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 14 Sep 2022 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues to 1st August 22 nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to non conformances that

need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review the above

### 16 Sep 2022 Derek Lamb

Reviewed ok

#### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
268177 05 Aug 2022	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

### 10 Aug 2022 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Checked back through all Non Conformance issues to 1st July 22 nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Review VST Product Feedback Positive (1190) nothing new. Review VST Feedback - Customer Feedback Negative (740) nothing new. Review VST Customer Feedback Positive(1191) nothing new. Review VST Feedback - Customer Complaints (738) nothing new. No other feedback issues relating to non conformances that need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about. Derek please review

### 10 Aug 2022 Derek Lamb

reviewed

#### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint	Reviewed Non Conformity / Complaint and	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance	Effectiveness of corrective action reviewed
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		/ No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	determine if its a vigilance issue requiring a corrective action plan					or regulatory requirements
267039 25 Jul 2022 265294	Non conformance review history VST (285) tasks	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Derek Lamb Added by Helen Lamb sent to Derek Lamb Positive feedback re product VST. No Task for this to be reviewed Positive feedback re customer VST. No Task for this to be reviewed Think we should have tasks for these</p>								
<p><b>25 Jul 2022 Helen Lamb</b> there are two other issues tasks but they seem a general ones. Tasks 1068 and 1069</p>								
<p><b>25 Jul 2022 Derek Lamb</b> added today as processes with linked tasks</p>								
<p><b>29 Jul 2022 Helen Lamb</b></p>								
<p>Non Conformance Issues VST</p>								
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
265294 05 Jul 2022	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Helen Lamb**

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

**25 Jul 2022 Helen Lamb**

Created Related Issue #267039

Added by Helen Lamb sent to Derek Lamb

Positive feedback re product VST. No Task for this to be reviewed Positive feedback re customer VST. No Task for this to be reviewed Think we should have tasks for these

**25 Jul 2022 Helen Lamb**

Checked back through all Non Conformance issues to 1st June 22 nothing of concern or to be investigated or reported on. Review VST Product Feedback Negative (742) nothing new. Positive feedback re product nothing new. No Task for this to be reviewed Review VST Feedback - Customer Feedback Negative (740) nothing new. Positive feedback re customer nothing new. No Task for this to be reviewed Review VST Feedback - Customer Complaints (738) No other feedback issues relating to non conformances that need to be monitored or reviewed. Order Invoice Error Logs - no issue, nothing to worry about.

Audit Training  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
264799 30 Jun 2022	Audit 08 Training Viamed (10)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Derek Lamb**

System Generated Audit 08 Training BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**14 Jul 2022 Helen Lamb**

Audit completed Derek, scanned and uploaded by Helen Second scan is in the correct page order

**21 Jul 2022 Derek Lamb**

Done

Audit Documentation Control VST									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
<a href="#">262667</a> <a href="#">10 Jun 2022</a>	Audit 10 Documentation Control VST (183)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Derek Lamb

System Generated Audit 10 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**07 Jul 2022 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Audit completed no issues, please review

**07 Jul 2022 Derek Lamb**

thank you

Non Conformance Issues  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		to Escalate Non conformance / or dealt with in s							
<a href="#">262009</a> <a href="#">06 Jun</a> <a href="#">2022</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

#### 06 Jun 2022 Helen Lamb

checked back through all Non Conformance issues to 1st May 22 nothing of concern or to be investigated or reported on. Negative feedback re product nothing new. Positive feedback re product nothing new. Negative feedback re customer nothing new. Positive feedback re customer nothing new. No other feedback issues relating to non conformances that need to be monitored or reviewed Order Invoice Error Logs - no issue, nothing to worry about.

Non Conformance Issues  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">259203</a> <a href="#">05 May</a> <a href="#">2022</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

#### 06 May 2022 Helen Lamb

checked back through all Non Conformance issues to 1st April 22 nothing of concern or to be investigated or reported on. Order Invoice Error Logs - no issue, nothing to worry about. No feedback issues relating to non conformances that

need to be monitored or reviewed

### Audit Handling and Storage VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">257431</a> <a href="#">19 Apr 2022</a>	Audit 07 Handling And Storage VST (178)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 07 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**22 Apr 2022 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb VST Audit 07 Handling and stock 2022 attached Please review

**17 Jun 2022 Derek Lamb**

thanks

### Audit Goods Inwards and Product Identity VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		Failure but no requirement to Escalate Non conformance / or dealt with in s							
257393 14 Apr 2022 253497	Audit 09 Goods Inward And Product Identity VST (174)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Helen Lamb sent to Derek Lamb

q11 missing info from a srs 68092. think its a system issue

#### 04 Aug 2022 Derek Lamb

was a system bug, seem the account was tagged with a non existant contact ID, not sure why but it wasnt taking the correct number as things didnt match up. fixed.

#### Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
256229 05 Apr 2022	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

System Generated Check the history of the last Non conformance review, check actions are being carried out, and non conformances are not reoccurring. Review the Order Invoice Error Logs (link in issue) for increases in errors. Areas that are errors that are our mistake and not due to changes instigated by the customer. Note any problem areas in report. Review Customer Complaint and Non Conformance Review Screen check back over the previous month since last review to see if anything internal / staff / process related needs to be highlighted. Go to Add an issue, search non con and review any issues since the last review for internal / staff / process related issues that needs to be highlighted. Note any problems in the issue and send to Derek to review

#### 05 Apr 2022 Helen Lamb

checked back through all Non Conformance issues to 1st jan 22 nothing of concern or to be investigated or reported on. Order Invoice Error Logs - no issue, nothing to worry about. No feedback issues relating to non conformances that need to be monitored or reviewed

## Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">250131</a> <a href="#">04 Feb 2022</a>	Non conformance review history VST (286)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated

Check the below review is being carried out

Check the history of the last Non conformance review,

check actions are being carried out,  
and non conformances are not reoccurring**07 Feb 2022 Derek Lamb**

reviewed, nothing stands out as a problem

## Audit Picking and Packing

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		/ or dealt with in s							
246776 03 Jan 2022	Audit 01 Picking Packing VST (194)	<input checked="" type="checkbox"/>	<input type="checkbox"/>						

Derek Lamb

System Generated Audit 01 due BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**04 Mar 2022 Helen Lamb**

Priority Changed From 5 To 2

**13 Apr 2022 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb VST Audit completed as per old system as new system not ready Please review the attached.

**26 Apr 2022 Derek Lamb**

thankyou

**25 Jan 2023 Helen Lamb**

Created Related Issue #284669

Added by Helen Lamb sent to Helen Lamb

Both Viamed and VSt need a re write as reflects old system

Non Conformance Issues  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
244975 10 Dec 2021 244667	Audit 17 Internal Audits VST (191) Non Conformance	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Derek Lamb sent to Derek Lamb

Need a QC21 form to look into this, there should not be blank sections of the standard with regard to an area being audited, unless the section is just the Title of the section. the blanks appearing are define sub sections so no reason to be blank.

**13 Dec 2021 Derek Lamb**

sorted

## Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
241419 08 Nov 2021	Shipped Items Return to Supplier BOX828	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Does this Return BOX828 warrant a NON conformance report via the CAPA process VM3COP10

**10 Nov 2021 Derek Lamb**

VST normal oxyegen sensor fails no capa required

## Complaints

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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<a href="#">239983</a> <a href="#">26 Oct 2021</a>	Objective All complaints to be logged and All complaints to be satisfactorily resolved in 6 months	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
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## General

26 Oct 2021 Derek Lamb

No New complaints in the Complaint headers,

Is an Issue/repair with JFD regarding the failure of 1 sensor during a test, not at this time a complaint, but they want to know what the failure is.SRS67874

Audit Management Review  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">238809</a> <a href="#">15 Oct 2021</a>	Audit 18 Management Review VST (188)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 18 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**15 Oct 2021 Helen Lamb**

Priority Changed From 5 To 1

**26 Oct 2021 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb audit attached, issues that are outstanding are noted on the viamed audit

**26 Nov 2021 Derek Lamb**

thankyou

Non Conformance Issues VST									
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed	
237792 05 Oct 2021	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Derek Lamb  
System Generated  
Check the history of the last Non conformance review,

check actions are being carried out,  
and non conformances are not reoccurring

#### 07 Oct 2021 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb This is in the process of being built so some functions are not present yet. Most changes to orders are due to the customer making changes. Orders deleted is the highest over the last two months and due to lack of stock- lead times and unpaid proformas. Updates to carriage is the second highest and is due to the customer changing method due to recent delays in shipping by other methods. Covid and Brexit have caused shipping issues recently. No problems stick out and no remedial action is needed on the current figures in the Reasons for opening Orders For Editing page Customer Complaint and Non Conformance Review Screen Nothing since last review re internal errors or areas of concern. Non Conformance Issues - Non Conformance Issues. There is nothing relating to - internal / staff / processes No issues ongoing overall and no problem areas - Viamed

#### 07 Oct 2021 Derek Lamb

thank you

#### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	corrective action plan						
234773 06 Sep 2021	Shipped Items Return to Supplier BOX809	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
Does this Return BOX809 warrant a NON conformance report via the CAPA process VM3COP10

**06 Sep 2021 Derek Lamb**  
vst Low Output sensor, normal fail tpe no capa required at this point

Audit Analysis of Data  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
233619 24 Aug 2021 228924	Audit 23 Analysis Of Data VST (185)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
Added by Helen Lamb sent to Derek Lamb  
Stock Meeting last done april now due

**09 Sep 2021 Derek Lamb**  
done

Audit Analysis of Data  
VST

Issue / Primary	Subject/Notes	Minor Internal Error i.e. not ISO	Reviewed Non Conformity	Determined Cause of Non	Evaluated action to Ensure	Planning and documenting action needed	Verify Action does not adversely	Effectiveness of corrective
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ID / Call ID	Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	/ Complaint and determine if its a vigilance Issue requiring a corrective action plan	Conformity / Complaint	does not recur	and implementation QC 28b	affect Safety	Performance or regulatory requirements	action reviewed
<a href="#">228924</a> <u>13 Jul 2021</u>	Audit 23 Analysis Of Data VST (185)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 23 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**24 Aug 2021 Helen Lamb**

Created Related Issue #233619

Added by Helen Lamb sent to Derek Lamb

Stock Meeting last done april now due

**25 Aug 2021 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb audit done and attached #233619 ongoing issues

**17 Sep 2021 Derek Lamb**

Done

Audit Analysis of Data VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		conformance / or dealt with in s							
228026 05 Jul 2021	Review Company Data (114)	<input checked="" type="checkbox"/>	<input type="checkbox"/>						

Derek Lamb  
System Generated

Sales Menu ->

Analysis of Data Viamed Analysis of Data VST

Search for any potential problems in the Graphs provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Search the Outstanding Jobs column for potential problems Do we have enough resources. Check the Issues Statistics in the meeting header, Check Issues are being completed in a timely manner.

**05 Aug 2021 Derek Lamb**

board meeting held 3 aug 2021 all data was reviewed

Audit Documentation Control  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
225277 10 Jun 2021	Audit 10 Documentation Control VST (183)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 10 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**01 Jul 2021 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb one issue pending related to this 227413. Audit completed and attached

## Audit Calibration

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">223116</a> <a href="#">20 May 2021</a>	Audit 06 Calibration VST (182)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 06 BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**25 Aug 2021 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb audit done, and attached. No issues outstanding VST doesn't actively use Test equipment as not testing before despatch.

**09 Sep 2021 Derek Lamb**

Done

## Audit Analysis of Data

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		Non conformance / or dealt with in s						
221537 05 May 2021	Review Company Data (114)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
System Generated

Sales Menu ->

Analysis of Data Viamed Analysis of Data VST

Search for any potential problems in the Graphs provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Search the Outstanding Jobs column for potential problems Do we have enough resources. Check the Issues Statistics in the meeting header, Check Issues are being completed in a timely manner.

#### 05 May 2021 Derek Lamb

Helen been on holiday 1 outstanding task overdue, MG on tidying his room, RS Distributor Agreements, t/o dropped in april, need to see how may goes

#### Audit Production VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
221169 03 May 2021	Audit 15 Production VST (175)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
System Generated Audit 15 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

#### 04 Aug 2021 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb audit complete some outstanding issue attached to Viamed Audit that relate to both Viamed and VST

**11 Aug 2021 Derek Lamb**

Tasks have been completed

## Audit Post Marketing Surveillance

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">221043</a> <a href="#">30 Apr 2021</a>	Audit 22 Post Market Surveillance Viamed (14)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 22 BSI Audits Calendar BSI Audit Post Marketing Surveillance BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**01 Jul 2021 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Audit completed no ongoing issues

## Audit Handling and Storage

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		requirement to Escalate Non conformance / or dealt with in s							
<a href="#">219542</a> <a href="#">15 Apr 2021</a>	Audit 07 Handling And Storage VST (178)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 07 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**11 Jun 2021 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb done please see audit attached. No Issues with VST

**15 Jun 2021 Derek Lamb**

thankyou

Non Conformance Issues  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">218313</a> <a href="#">06 Apr 2021</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

System Generated

Check the history of the last Non conformance review,

check actions are being carried out,  
and non conformances are not reoccurring

**07 Apr 2021 Helen Lamb**

**13 May 2021 Helen Lamb**

There do not appear to be any inherent problems / frequently occurring issues. When a mistake has been made those

responsible have been spoken to and the relevant process re gone over. So the same mistake / error doesn't happen again.

### Audit CE Files VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
217140 22 Mar 2021	Audit 12 CE Files VST (176)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 12 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 01 Jul 2021 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Audit done no ongoing issues

### Audit Goods Inwards and Product Identity VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		Non conformance / or dealt with in s							
	<a href="#">215995</a> <a href="#">09 Mar</a> <a href="#">2021</a>	Audit 09 Goods Inward And Product Identity VST (174)	<input checked="" type="checkbox"/>	<input type="checkbox"/>					

Derek Lamb

System Generated Audit 09 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**22 Jun 2021 Helen Lamb**

Created Related Issue #226589

Added by Helen Lamb sent to Derek Lamb

question 16 Quarterly meetings. We do for Viamed, but VST they are annually carried out. Is this ok and correct

**01 Jul 2021 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb one issue pending related to this 220469. Audit completed and attached

Non Conformance Issues  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">212854</a> <a href="#">04 Feb</a> <a href="#">2021</a>	Non conformance review history VST (286)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated

Check the below review is being carried out

Check the history of the last Non conformance review,

check actions are being carried out,  
and non conformances are not reoccurring

**11 Feb 2021 Derek Lamb**

202853, needs closing, when we get to hold a vst meeting

## Audit Analysis of Data

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
209745 05 Jan 2021	Review Company Data (114)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
System Generated

Sales Menu -&gt;

## Analysis of Data Viamed Analysis of Data VST

Search for any potential problems in the Graphs provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Search the Outstanding Jobs column for potential problems Do we have enough resources. Check the Issues Statistics in the meeting header, Check Issues are being completed in a timely manner.

**05 Jan 2021 Derek Lamb**

issues system upto date, no old employees, Turnover best on record.

Audit Picking and Packing  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		Failure but no requirement to Escalate Non conformance / or dealt with in s							
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209457 04 Jan 2021	Audit 01 Picking Packing VST (194)	<input checked="" type="checkbox"/>	<input type="checkbox"/>						
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Derek Lamb

System Generated Audit 01 due BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 27 Jan 2021 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb audit completed and attached

### 27 Jan 2021 Derek Lamb

thanks no follow on issues

### Audit Analysis of Data VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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206996 07 Dec 2020	Review Company Data (114)	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
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Derek Lamb  
System Generated

Sales Menu ->

Analysis of Data Viamed Analysis of Data VST

Search for any potential problems in the Graphs provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Search the Outstanding Jobs column for potential problems Do we have enough resources. Check the Issues Statistics in the meeting header,

Check Issues are being completed in a timely manner.

**07 Dec 2020 Derek Lamb**

reviewed, a few issues starting to stack up, but non that require immediate attention, will check again end of week

**Audit of Audits**

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">206391</a> <a href="#">01 Dec 2020</a>	Audit 21 Audit Of Audit VST (192)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 21 due Review the Audit Calendar Screen ISO -> Audit Calendar Complete Audit 21 Confirm if Audit calendar needs changing. BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**13 Oct 2021 Helen Lamb**

audit attached as requested

**13 Oct 2021 Derek Lamb**

thanks

**Audit Internal Audits**

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested /	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		Product Failure but no requirement to Escalate Non conformance / or dealt with in s						
206390 01 Dec 2020	Audit 17 Internal Audits VST (191)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 17 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

#### 04 Dec 2020 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb done

#### 11 Feb 2021 Derek Lamb

Audit Analysis of Data  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
203695 05 Nov 2020	Review Company Data (114)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
System Generated

Sales Menu ->

Analysis of Data Viamed Analysis of Data VST

Search for any potential problems in the Graphs provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Search the Outstanding Jobs column for potential problems Do we have enough resources. Check the Issues Statistics in the meeting header,

Check Issues are being completed in a timely manner.

**05 Nov 2020 Derek Lamb**

reviewed with bsi last week

BSI Minor Non conformances

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
202983 29 Oct 2020 155085	vst exclusions	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

Added by Derek Lamb sent to Derek Lamb

Note VST also now requires an exclusion to 9001 adding will update when bsi approves viameds Next Action Changed From Derek Lamb To Helen Lamb

**29 Oct 2020 Derek Lamb**

found document in index already 23739 Internal use only VM3COP02.01 Boundaries ISO 9001:2015 VST

Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		conformance / or dealt with in s						
202853 28 Oct 2020	Service Repair Sheet:67494	<input checked="" type="checkbox"/>	<input type="checkbox"/>					

Steve Nixon

Added by Derek Lamb sent to Derek Lamb

**Service Repair Sheet:67494** SRN32620 Oxygen Sensor VST 8010050 100587 Oxygen Sensor - JFD (non-mag).. Account Non Conformance should have been raised against the sensors with incorrect body size

**28 Oct 2020 Derek Lamb**

Header Changed From 202 VIAMED Stock Repairs Review - General To VST Management Non Conformance Issues

**28 Oct 2020 Derek Lamb**

Next Action Changed From Derek Lamb To Steve Nixon Noted its Envitec Issue, however its as close to a customer complaint, via a product return. as the size was incorrect, Due to being in covid lock down and the urgency to get these turned around, a non conformance was not raised. As we do not test the sensors from Envitec we will not catch these in the future, could do with finding a response from Envitec as to what they have done to stop this happening again. We may already have this in the system, but it need printing and attaching to this issue.

**15 Nov 2021 Derek Lamb**

see srs 67494

Audit Management Review

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
200801 15 Oct 2020	Audit 18 Management Review VST (188)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 18 BEFORE starting the Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

**19 Oct 2020 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb done please review this and check you are happy with it

**11 Feb 2021 Derek Lamb**

thanks

Non Conformance Issues

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
199461 05 Oct 2020	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb

System Generated

Check the history of the last Non conformance review,

check actions are being carried out,  
and non conformances are not reoccurring

**09 Oct 2020 Helen Lamb**

No errors reoccurring

Audit Analysis of Data

VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
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		to Escalate Non conformance / or dealt with in s							
<a href="#">199451</a> <a href="#">05 Oct</a> <a href="#">2020</a>	Review Company Data (114)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
System Generated

Sales Menu ->

Analysis of Data Viamed Analysis of Data VST

Search for any potential problems in the Graphs provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Search the Outstanding Jobs column for potential problems Do we have enough resources. Check the Issues Statistics in the meeting header, Check Issues are being completed in a timely manner.

#### 07 Oct 2020 Derek Lamb

Check Audit Roles Titles and Processes in Employee Roles and Titles. Done, updated to make easier mass closing of relevant issues if there is a back log , and the backlog reason is fixed (i.e. covid build up non essecial jobs) While resources have been tight personel wise, we have show we can deal with a sudden large through put of stock Issue statistics now broken,

#### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">198689</a> <a href="#">25 Sep</a> <a href="#">2020</a>	Shipped Items Return to Supplier BOX741	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb  
Does this Return BOX741 warrant a NON conformance report via the CAPA process VM3COP10

#### 28 Sep 2020 Derek Lamb

VST sensors, no cap required

#### Non Conformance Issues VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">172324</a> <a href="#">06 Apr 2020</a>	Non conformance review history VST (285)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb  
System Generated  
Check the history of the last Non conformance review,

check actions are being carried out,  
and non conformances are not reoccurring

**23 Apr 2020 Helen Lamb**  
nothing on going for VST

Any New QC21 Forms  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">167500</a> <a href="#">03 Mar 2020</a>	QC 21 Form Oxygen Sensor -	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	R17JJ-CCR Shipment Dates							
Derek Lamb	Added by Derek Lamb sent to Derek Lamb	JJCCR usually place a forward order, and need reminding when to place another order, this month the reminder was late, and while we have stock in the pipeline, Jan will usually want the sensors at the start of the month, Our required date on next supplier order was set as the 4th March, When the confirmation came in on the 3rd feb, and the estimate shipping date correctly filled in it was for the date 11th March. the dates mismatch was not picked up by office staff while confirming the order						
<b>03 Mar 2020 Derek Lamb</b>	Rasised a QC21 Form due to the fact the customer is un happy, and his stock is going to be a week later than planned							
<b>11 Mar 2020 Derek Lamb</b>	Created Related Issue #168340 Added by Derek Lamb sent to Catrin Hird							
<b>09 Apr 2020 Derek Lamb</b>	Header Changed From 503 VST Management Non Conformance Issues To Non Conformance Issues Any New QC21 Forms Urgent Flag Changed To On Subject Changed From Oxygen Sensor - R17JJ-CCR Shipment Dates Subject Changed To QC 21 Form Oxygen Sensor - R17JJ-CCR Shipment Dates							
<b>10 Apr 2020 Derek Lamb</b>								
	Non Conformance Issues VST							
Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">164203</a> <a href="#">04 Feb 2020</a>	Non conformance review history VST (286)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Derek Lamb System Generated Check the below review is being carried out	Check the history of the last Non conformance review,							

check actions are being carried out,  
and non conformances are not reoccurring

### 12 Mar 2020 Derek Lamb

upto date as feb

Audit Picking and Packing  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
161466 02 Jan 2020	Audit 01 Picking Packing VST (194)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 01 due BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document Index Admin Document - Copy and Paste List Processes Per Title replacing them in the current audit. Review Last years Audit see if its still suitable Carry out the Audit, reviewing and commenting on the ISO route map first. If there are any non Conformances from the Audit, create a follow up / related Issue including all of the following - With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution If its a major / critical non conformance complete form QC 18

### 08 Jan 2020 Helen Lamb

Priority Changed From 5 To 2

### 10 Sep 2020 Helen Lamb

Created Related Issue #196533

Added by Helen Lamb sent to Sarah Walton

Order ID RST124142 has no customer paperwork attached. Please can you find the paperwork and add it also please make sure to add customer paperwork to all orders.

### 23 Sep 2020 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb Audit completed and attached, please check you are happy with this and let me know if you have any queries.

### 28 Sep 2020 Derek Lamb

checked and ok

Audit Design Control  
VST

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
<a href="#">161465</a> <a href="#">02 Jan 2020</a>	Audit 03 Design Control VST (193)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Derek Lamb

System Generated Audit 03 NOTE DESIGN REMOVED FROM VST, AUDIT NOT REQUIRED. LEFT IN FOR FUTURE USE Review Last years Audit see if its still suitable Before Proceeding you need to update the Processes attached to the Audit Search the Document in the Index, View the Admin Page Copy and Paste the Attached Processes, replacing them in the current audit Any non Conformances from the Audit: Create a follow up / related Issue, With a time for Completion Immediate Action Plan Corrective Action Plan Corrective Action Confirmation of Resolution if its a major / critical non conformance complete form QC 18

**08 Jan 2020 Helen Lamb**

Priority Changed From 5 To 2

**23 Sep 2020 Helen Lamb**

Next Action Changed From Helen Lamb To Derek Lamb Audit completed and attached, please check you are happy with this and let me know if you have any queries.

**28 Sep 2020 Derek Lamb**

checked ok, no viamed design,