

		conformance / or dealt with in s						
375175 11 Sep 2025	BSI Non Conformance 2700663-202509-N2	<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 Helen Lamb

The medical devices files process of the organisation is not fully effective, as the organisation has not established requirements to Nonconformity Report Page 4 of 9 ensure that product labelling is up to date and viable. The organisation has not documented labelling requirements as a distributor to verify or maintain product labels implemented and placed by the legal manufacturers are current, compliant and remain legible throughout distribution. Technical files were seen historic, predating the sampled product and existing labels on product was seen not recorded. The product sampled was in relation to Temperature Probe – Skin Contact – Ref 1010132021V – SN 210114478 – Type 0212921 – Viamed Ltd – Produced Oct 2021 – Barcode ID 1856344 – Manufacturer Bluepoint Medical GmbH # Interface Agreement – Bluepoint medical GmbH & Co KG – 21/12/2016

11 Sep 2025 Helen Lamb

I have filled in some fields it will need reviewing and adding to but its a start. HL V1

BSI Minor Non conformances

Viamed Vandagraph VST 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
375173 11 Sep 2025	BSI Non Conformance 2700663-202509-N1	<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 Helen Lamb

The internal audit process is not fully effective as raised issues within audit records do not clearly differentiate between observations and non-conformities. Audit records reviewed (Audit 15 and Audit 06) highlighted issues and were raised within the Intrastat (eQMS system). The issues raised did not highlight or state if the issues were an observation or non-conformance. No investigation or CAPA related actions were seen and the issues were cleared/completed with note comment only. # Audit 06 – Performed 30 May 2025 – Issues 365729 Raised 26 June 2025; Issue 367474 Raised 18 June 2025 – Closed 26 June 2025 # Audit 15 – Performed 21 July 2025 – Issues 370409, 370410 – Raised 21 July 2025 – Closed 22 July 2025

11 Sep 2025 Helen Lamb

My first version is attached please review it and see if im on the right track. Once we are happy i will start doing the corrective actions

Non Conformance Issues

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
374604 05 Sep 2025	Non conformance review history Viamed (283)	<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
H.S.E. implications :No health and safety implications

05 Sep 2025 Helen Lamb

Checked back through all Non Conformance issues (not automatically generated) to 1st September 25. Nothing Of concern or to be investigated or reported on in Non Con issues. Review VIAMED Feedback - Product Feedback Negative (741) nothing new. Review VIAMED Feedback - Product Feedback Positive (1189) nothing new. Review VIAMED Feedback - Customer Feedback Negative (739) nothing new. Review VIAMED Feedback - Customer Feedback Positive (1188) nothing new. Review VIAMED Feedback - Customer Complaints (737) nothing new. Order Invoice Error Logs - only one data entry error no other issue, nothing to worry about. Non Conformance, complaints and feedback headers issue re not fulfilling orders on website. Staff have been reminded to do this. Nothing new no concerns. Non Conformance issues review screen - No issues not already reviewed above in log. No other feedback issues relating to non conformances that need to be monitored or reviewed. Derek please review the above Done

Audit Analysis of Data

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 /	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						
374598 05 Sep 2025	Review Company Data (114)	<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 Review Sales - Number Invoices / Credits per day reports Search for any potential problems in the Data provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Check the Page for Red Crosses and potentially missing objectives 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.

H.S.E. implications :No health and safety implications

11 Sep 2025 Derek Lamb

done

Non Conformance Issues

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
374520 04 Sep 2025	Order Error : 158513 Vandagraph 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

Auto Issue from Error Log 158513

Order Entered by Aqib Majeed

Order Checked by Michael Lamb

Goods Out

Error was Vandagraph

New Error

Fault:

Order not fulfilled on Shopify

Possible Fix

Done

04 Sep 2025 Helen Lamb

I have chased this again but also added a process and rolling issue to try and stop this happening Done

Audit Documentation Control

Viamed Vandagraph VST 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
374309 03 Sep 2025	Documentation out of date (372)	<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 for Out of Date documents

This is an audit, you do not need to perform the Task:

Simply ensure all out of date documents have an Issue attached to get them updated.

If the Issue is more than 2 Months out of date read the issue - if appropriate generate a non conformance Issue

ISO - Document index admin

Scroll down and check if any documents have gone out of date,

Either update the document or create an Issue to the relevant person from the document admin / details screen.

Remember if you update a document reset the expiry date

H.S.E. implications :No health and safety implications

03 Sep 2025 Helen Lamb

Done

Audit Contract Review 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
373972 01 Sep 2025	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
H.S.E. implications :No health and safety implications

03 Sep 2025 Helen Lamb

Audit completed no non conformances. Nothing outstanding and nothing ongoing. Please review

03 Sep 2025 Derek Lamb

thankyou

Audit Purchasing 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
373965 01 Sep 2025	Audit 05 Purchasing Suppliers Viamed (37)	<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 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
H.S.E. implications :No health and safety implications

08 Sep 2025 Helen Lamb

Completed Audit attached, no outstanding issue. No non conformances. Please review

09 Sep 2025 Derek Lamb

thankyou

Audit Contract Review 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
373964 01 Sep 2025	Audit 02 Contract Review Viamed (36)	<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
H.S.E. implications :No health and safety implications

03 Sep 2025 Helen Lamb

Audit completed no non conformances. Nothing outstanding and nothing ongoing. Please review

03 Sep 2025 Derek Lamb

thankyou

Non Conformance Issues 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
373734 27 Aug 2025	Shipped Items Return to Supplier BOX1044	<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 BOX1044 warrant a NON conformance report via the CAPA process VM3COP10

27 Aug 2025 Derek Lamb

8010006 various output errors normal for o2 sensors no cap required recent failure rate (0.31 %)

Non Conformance Issues 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
373624 27 Aug 2025	Order Error : 158466 Viamed 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

Auto Issue from Error Log 158466

Order Entered by Aqib Majeed

Order Checked by Sophie Lines

Non Selected

Error was Viamed

New Error

Fault:

website error - order not fulfilled on website

Possible Fix

done

27 Aug 2025 Helen Lamb

Done

Non Conformance Issues 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
373242 20 Aug 2025	Filling in or entering an SRS Please tag them correctly	<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

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

Anyone filling in a SRS please can you make sure that you tag them correctly. The repair/quote option Is being set to Repair or Service/Calibration, When it should say Quote . It should only be turned from quote to Repair or Service/Calibration when we have the customer purchase order.

20 Aug 2025 Helen Lamb

Done

Non Conformance Issues Viamed								
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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
373120 19 Aug 2025	Order Error : 158339 Viamed Carriage - office	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Helen Lamb
Auto Issue from Error Log 158339
Order Entered by Sophie Lines
Order Checked by Kate Griffiths
Office
Error was Viamed
Carriage - office
Fault:
put the export ups express saver on a UK order

Possible Fix
sent back to office for them to amend

20 Aug 2025 Helen Lamb
done

Non Conformance Issues 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
373092 19 Aug 2025	Shipped Items Return to Supplier BOX1043	<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 BOX1043 warrant a NON conformance report via the CAPA process VM3COP10

20 Aug 2025 Derek Lamb
4410540 The unit has a red ring ISA fault returning to supplier no cap required by us

Non Conformance Issues 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
373079 19 Aug 2025 363316	Repairs details not being entered correctly	<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 Robert Connor sent to Helen Lamb
Still no improvement, it's the same as ever

Audit Contract Review Viamed

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring	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	Effectiveness of corrective action reviewed
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		required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	a corrective action plan					regulatory requirements	
372880 18 Aug 2025	Distributor Agreements (379)	<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

Note this is an Audit - simply need to ensure its being carried out

Sales -> Distributor Agreements -> Check Sales Against Agreements,

List should be up to date / empty.

H.S.E. implications :No health and safety implications

19 Aug 2025 Derek Lamb

some on list but only a few distributors, so the list is being maintained

Audit Organisation and Process Verification Internal Process Verification

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
372877 18 Aug 2025	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"/>

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

H.S.E. implications :No health and safety implications

19 Aug 2025 Derek Lamb

main box has been done, all upto date

Non Conformance Issues

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
372591 13 Aug 2025	Shipped Items Return to Supplier BOX1042	<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 BOX1042 warrant a NON conformance report via the CAPA process VM3COP10

13 Aug 2025 Derek Lamb

Supplier Return ? Summary (BOX?1042) #Stock RefSupply RefBar?codeSerial No.Fault / IssueCountry of OriginCustoms ValueEst. Date inAdded to BOX?1042Added By 10110040??V108401Leaking gasesGermany€?5.0003?Mar?202501?Aug?2025Catherine?Spence 20110040??V108402Leaking gasesGermany€?5.0003?Mar?202501?Aug?2025Catherine?Spence 30110040??V108403Leaking gasesGermany€?5.0003?Mar?202501?Aug?2025Catherine?Spence 40110049??V104860UnstableGermany€?5.0019?Dec?202401?Aug?2025Catherine?Spence 50110182??V118077No OutputGermany€?5.0028?Apr?202501?Aug?2025Catherine?Spence Key Points ItemTotal ValuePrimary IssueNumber of Units 0110040 (3 units)€?15.00Leaking gases3 0110049 (1 unit)€?5.00Unstable1 0110182 (1 unit)€?5.00No output1 Grand Total€?25.00?5 Operations Overview Print RMA Request PDF ? All items are ready for RMA processing; PDFs are queued for printing. Add Items from Print Queue ? The five items above have already been added to the print queue for shipment. Non?Serial/Bar?coded Items ? All units are non?serial and bar?coded, so the system uses ?N/A? for the serial number field where applicable. Customs Information ? Each item is from Germany, with a declared customs value of €?5.00. Shipping Invoice / Fault Sheets ? Fault sheets are generated using the serial numbers provided (e.g., V108401). Boxing / Packaging ? All items are listed under BOX?1042 with the same ?Date Added? (01?Aug?2025) for consistency in the packing list.

13 Aug 2025 Derek Lamb

reviewed no cap required

Non Conformance Issues

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
372212 08 Aug 2025	Shipped Items Return to Supplier BOX1041	<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 BOX1041 warrant a NON conformance report via the CAPA process VM3COP10

11 Aug 2025 Derek Lamb

sensor output errors, no cap required

Non Conformance Issues
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
371760 05 Aug 2025	Non conformance review history Viamed (283)	<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

H.S.E. implications :No health and safety implications

08 Aug 2025 Helen Lamb

Checked back through all Non Conformance issues (not automatically generated) to 1st August 25. 370242 Manufacturing defect, the sensor is leaking at the O ringno cap required returning to supplier, 370602 Calibrate button not working, Nothing else of concern or to be investigated or reported on in Non Con issues. Review VIAMED Feedback - Product Feedback Negative (741) nothing new. Review VIAMED Feedback - Product Feedback Positive (1189) nothing new. Review VIAMED Feedback - Customer Feedback Negative (739) nothing new. Review VIAMED Feedback - Customer Feedback Positive (1188) nothing new. Review VIAMED Feedback - Customer Complaints (737) nothing new. Order Invoice Error Logs - No issue, nothing to worry about. Non Conformance, complaints and feedback headers. 368629, 368630, 368631, 368990, 369141, 369316, 369493, 369494, 369991, 370005 errors covered in the error log. Issue 367345 missing sensors from Maxtec. Nothing else and nothing of concerns. Non Conformance issues review screen - No issues not already reviewed above in log.No other feedback issues relating to non conformances that need to be monitored or reviewed.Derek please review the above

08 Aug 2025 Derek Lamb

thankyou

Audit Analysis of Data
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
371755 05 Aug 2025	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 Review Sales - Number Invoices / Credits per day reports Search for any potential problems in the Data provided

Employee Menu Check Audit Roles Titles and Processes in Employee Roles and Titles. Check the Page for Red Crosses and potentially missing objectives 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.

H.S.E. implications :No health and safety implications

05 Aug 2025

done, still need to remove SH from th eprocess logs

05 Aug 2025 Derek Lamb

done

Future Reviews - Internal Audits 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
371570 01 Aug 2025	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
01 Aug 2025 Derek Lamb
audits ongoing

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
371545 01 Aug 2025	Objective: All complaints to be logged, contained / risk controlled in 10 Days and All complaints to be satisfactorily resolved in 6 months (I)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

General
01 Aug 2025 Derek Lamb
no complaints

Audit Repairs and Service 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
371427 01 Aug 2025	Audit 24 Due Servicing (288)	<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 24 Due Servicing 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
H.S.E. implications :No health and safety implications
15 Aug 2025 Derek Lamb
thankyou

Audit Health and Saftey 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	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

		Escalate Non conformance / or dealt with in s						
371416 01 Aug 2025	Audit 19 Health And Saftey Viamed (13)	<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</p> <p>System Generated Do HSE Audit Audit No 19. Send out HSE Personnel Questionnaire, and the HSE DSE Personnel Questionnaire and reissue message of the day reminding users all HSE Documents are available in Intrastats 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</p> <p>H.S.E. implications :No health and safety implications</p> <p>29 Aug 2025 Helen Lamb</p> <p>Completed Audits attached, No outstanding issues, no non conformances. Please review</p> <p>29 Aug 2025 Derek Lamb</p> <p>thankyou Done</p>								
Non Conformance Issues 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
371116 29 Jul 2025	Shipped Items Return to Supplier BOX1039	<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</p> <p>Does this Return BOX1039 warrant a NON conformance report via the CAPA process VM3COP10</p> <p>29 Jul 2025 Derek Lamb</p> <p>Here's a summary of failure reports and related QA activity for the Vandagraph VST Sensors (Part 8010007) covering the period 29 Jul 2023 ? 30 Jul 2025: Product Overview Part Number: 8010007 (VST Oxygen Sensor Module) Total Units Booked In (2 Years): 3,950 Total Units in System: 3,943 Installations span: Multiple SOs with new membrane implementations as of Oct 2024 Main configuration: OOD103 variants with individual sensor serial ranges tracked Fault Summary Global Failures (All Time): Total Global Failures Recorded: 68 faults out of 18,650 units in the system Warranty Failures: 57 (??0.31%) Non-Warranty Failures: 11 (??0.06%) No Fault Found cases: 44 (not included in fault rate) Unique Faults (29 Jul 2023 ? 30 Jul 2025): High Output: 1 Low Output: 2 Unstable Output Signal: 1 All from same product code (8010007), using sensor E1001581 Customer Return Timing (from invoice to failure): Fault Type3 Mo4 Mo10 Mo11 Mo Unstable Output Signal1 High Output1 Low Output11 Batch QA Observations Known batches received between Aug 2023 and May 2025 4 warranty failures found across multiple batches Most returns booked from Feb to May 2024, with no significant cluster after May 2024 Single unit returns tracked with serials, e.g. SN 100016?100027 (SO 263031148) ? Breakdown by Fault Code Fault CodeCountFault TypeNotes No Output11FaultMinor occurrence Low Output6FaultIncludes demo/customer returns Unstable Output Signal34FaultHighest single-code fault Linearity Error2FaultNo recent spike Zero Offset Signal Out Of Tolerance4FaultStable trend Output Cap Detached2FaultNo trend High Output4FaultNo spike PCB Corrosion / Connector Corrosion8No FaultLikely environmental Electrolyte Leakage2FaultUncommon PCB Movement Within Casing2FaultHardware issue Connector - unstable connection1FaultSingle instance Total QA-faulted units (true hardware or performance faults): 68 Non-Conformance Risk Review: Currently not triggered (no fault code exceeds 5% failure rate) Monthly Fault Trends No spikes in any month from Jan to Jun 2025; returns remain low volume and evenly spread. ? Risk Assessment Summary Overall Fault Rate: Very low (<?0.4%) No fault code exceeds 5% threshold ? No non-conformance raised Environmental & assembly issues (corrosion, movement, connector) noted but infrequent Recommendations Continue tracking serial ranges against faults (especially post-Oct 2024 batches with new membranes) Monitor ?Unstable Output Signal? in future returns?has highest fault count globally Document all ?No Fault Found? cases separately to avoid skewing future metrics Audit OOD103-1V and similar variants more closely, as most faults relate to this configuration Let me know if you want this formatted as a report or added into a .docx, .xlsx, or presentation</p>								
Non Conformance Issues Viamed								
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371028 28 Jul 2025	Order Error : 158102 Viamed Address Error - Office	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Helen Lamb</p> <p>Auto Issue from Error Log 158102</p> <p>Order Entered by Ryan Swaine</p> <p>Order Checked by Aqib Majeed</p> <p>Vandagraph Office</p> <p>Error was Viamed</p> <p>Address Error - Office</p> <p>Fault:</p> <p>Postcode/ Zip code missed off order, even though it was in the address listed on the email</p> <p>Possible Fix</p>								