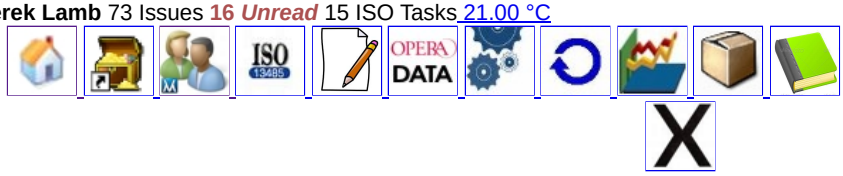
Backup Chat Live Chat Online

Derek Lamb 73 Issues **16** ***Unread*** 15 ISO Tasks 21.00 °C



QC 21 Active / Completed Forms Review Screen

Any Returns to Escalate Will Show Here :

Show All Returns Reviews

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

Any New QC21 Forms
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 / must state in issue if its an observation	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
378839 22 Oct 2025	QC 21 Non Conformance Report - We have labelled 25 Maxtec MAX55E 0110452 sensors as MAX250E 01104294, in goods in.	☐	☑	☑	☑	☑	☑	☑

Derek Lamb
Added by Helen Lamb sent to Derek Lamb
We have labelled 25 Maxtec MAX55E 0110452 sensors as MAX250E 01104294, in goods in. QC 21 form has been generated and attached. please review and add anything you think i may have missed. Once you have accepted this i`ll crack on with the corrective actions
22 Oct 2025 Helen Lamb
Done
22 Oct 2025 Helen Lamb
Email being sent out Important: Incorrectly Labelled Oxygen Sensors ? Action Required Inbox Sophie Lines Attachments 14:41 (1 hour ago) to deirdre.evans, cathy.green, Helen.lamb Good afternoon, I?m reaching out regarding your recent order with us ? 70004698. We?ve identified an issue affecting a batch of oxygen sensors that were incorrectly labelled as MAX-250E, while the sensors inside the packaging are a different type. Unfortunately, the 10x MAX-250E sensors shipped to you on 15th October are part of this batch (please refer to Line 1 on the attached delivery note). To resolve this promptly, we kindly ask that you return the affected units (if still in your possession) at your earliest convenience. A prepaid returns label will be emailed to you shortly for this purpose. We are also arranging for 10x correctly labelled MAX-250E sensors to be sent to you as soon as possible. We sincerely apologise for any inconvenience this may have caused and truly appreciate your cooperation in helping us correct the issue quickly. If you have any questions or need further assistance, please don?t hesitate to contact me. Kind regards Sophie Lines Office Administrator Viamed Ltd. Done
22 Oct 2025 Helen Lamb
Please review
22 Oct 2025 Derek Lamb
ok
24 Oct 2025 Derek Lamb
noted
07 Nov 2025 Derek Lamb
reviewed happy with this,
11 Dec 2025 Derek Lamb
Done

VIAMED Customer Complaints

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Issue / Primary	Subject/Notes	Minor Internal Error i.e. not ISO Non	Reviewed Non	Determined Cause of	Evaluated action to	Planning and documenting	Verify Action does not	Effectiveness of corrective

ID / Call ID		Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / must state in issue if its an observation	Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Non Conformity / Complaint	Ensure does not recur	action needed and implementation QC 28b	adversely affect Safety Performance or regulatory requirements	action reviewed
375262 12 Sep 2025 375260	Invoice RVM158724-1 8 extra 0110132 supplied by mistake	☐	☐	☐	☐	☐	☐	☐

Derek Lamb
Copy Issue Main Issue #375260
Added by Steve Nixon sent to Derek Lamb
Ref. invoice RVM158724-1 Ichinen have received 8 x 0110132 R-22AV sensors supplied to them FOC by mistake. They were offered these FOC, but they are unable to accept FOC goods. Serial numbers 2791148, 2791149, 2791150, 2791151, 2791174, 2791175, 2791176, 2791177 Ichinen have suggested that to resolve this they want to return 8 different sensors that are deemed to be faulty. Initially they will return 6 sensors, SRS Number 69240. Initial investigation alludes that 100 sensors were scanned to the order, but 108 were picked/packed.
12 Sep 2025 Helen Lamb
Derek can you fill in a non conformance form on this
12 Sep 2025 Derek Lamb
added files
19 Sep 2025 Helen Lamb
I have filled in the QC 21 form in. Derek please can you review it and fill in the Effectiveness verification Closed By: Closed on fields. I am happy we have resolved the issue and i think we should be in a good position to have this not happen again. We are working on what the customer wants. Their company policy is not to accept free goods, so they will be returning some different sensors that they think are faulty. So they are keeping the new ones sent in error. So they seem happy with the current status.

BSI Minor Non conformances

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375175 11 Sep 2025	BSI Non Conformance 2700663-202509-N2	☐	☐	☐	☐	☐	☐	☐

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

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		Product Failure but no requirement to Escalate Non conformance / must state in issue if its an observation	corrective action plan					
375173 11 Sep 2025	BSI Non Conformance 2700663-202509-N1	☐	☐	☐	☐	☐	☐	☐

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 / must state in issue if its an observation	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
351875 08 Jan 2025 351194	QC 21 Non Conformance Report - Incorrect oxygen sensors in boxes Non Conformance	☐	☑	☑	☑	☑	☑	☑

Derek Lamb
Added by Helen Lamb sent to Derek Lamb
From issue 351194. There have been some oxygen sensors that have been boxed, but have been placed in the wrong box with the wrong barcode attached. Original issue from Cathy 3rd January 25. To be investigated.

24 Feb 2025 Helen Lambthis has been resolved and no reoccurrence has happened. Staff have been re trained and a new policy where no different types of stock as placed together for boxing has been implemented. QC21 form needs to be updated

26 Feb 2025 Helen Lambthis has been resolved and no reoccurrence has happened. Staff have been re trained and a new policy where no different types of stock as placed together for boxing has been implemented. QC21 form needs to be updated

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 / must state in issue if its an observation	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
345017 25 Oct 2024 344455	Software Validation Document Control (802) Non Conformance	☑	☑	☑	☑	☑	☑	☑

Derek Lamb
Added by Derek Lamb sent to Derek Lamb
document did not appear, page has been reviewed as to the reason , seems the filter for pulling out documents, that are not linked to a

contact, failed, so we not showing the documents flagged as out of date, but not directly linked to a contact,. the bug has now been fixed, all documents are appearing,

25 Oct 2024 Derek Lamb
See QC 21 Form for document control.

13 Mar 2025 Derek Lamb
closed had enough time for any errors to show themselves

13 Mar 2025 Derek Lamb

27 Mar 2025 Derek Lamb
Done

Document Control Amendments needed

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330204 21 May 2024	Document Update Request (74728) QC 21 Non Conformance Form	☐	☐	☐	☐	☐	☐	☐

Helen Lamb
Added by Derek Lamb sent to Helen Lamb
Controlled Document (74728) QC 21 Non Conformance Form Requires Updating with regard iso nn conformances, we need to add what method we used for verification, and a time scale should be in the verification. we can say the cap is not effective, and try another method of corrective action, but we dont need to inform bsi of the further improvements. they will review them at nc closure

21 May 2024 Helen Lamb
Updated QC21 form attached please add to the system. Added Follow-up future issue id (Effectiveness verification) Date for Follow up review Issue to be carried out Effectiveness verification, statement of findings to be included in this report

Non Conformities 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 / must state in issue if its an observation	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
295339 16 May 2023	2342435-202305-N4 ISO 9001:2015 8.4 Minor	☑	☐	☐	☐	☐	☐	☐

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 control of suppliers is not fully effective as it was not observed that an agreement was in place to determine the controls applied to Viamend as a supplier. 8.4 Control of externally provided processes, products and services Viamed to VST PO: 143026 19 April 2023

16 May 2023 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

16 May 2023 Derek Lamb
see issue 295339

18 May 2023 Helen Lamb
hl revision added named 295339.12616 qc 21 initial document N4_18_05_23 HL1

21 May 2024 Helen Lamb
effectiveness verified and closed by Derek Lamb doc attached.

21 Jun 2024 Helen Lamb

20 Mar 2025 Helen Lamb
signed off by BSI 20 March 2025

Non Conformities 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 / must state in issue if its an observation	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	☑	☑	☑	☑	☑	☑	☑

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- conformity 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

21 May 2024 Helen Lamb
Effectiveness has been reviewed and completed. QC21 Non conformance has been closed by Derek Lamb today.

21 Jun 2024 Helen Lamb

20 Mar 2025 Helen Lamb
signed off by BSI 20 March 2025

BSI Minor Non conformances
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 / must state in issue if its an observation	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
269904 23 Aug 2022	VIAMED 2235543-202208-N1	☐	☑	☑	☑	☑	☑	☑

Helen Lamb
Added by Derek Lamb sent to Derek Lamb
The process of monitoring and measurement of product is not fully effective because the test equipment (multimeter) used to perform the final testing was not recorded.

23 Aug 2022 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

25 Aug 2022 Helen Lamb
my first draft attached QC 21 Initial investigation_25_08_22 VERSION 2 HL.doc

30 Aug 2022 Helen Lamb
changed some wording

09 Sep 2022 Helen Lamb
fixed the immediate action and moved some wording around

09 Sep 2022 Derek Lamb110301 110349 110350 110360 110361 110365 110410 110517 110950 111239 still todo

09 Sep 2022 Derek Lambdone, last item is monitor , not needing doing

09 Sep 2022 Helen Lamb

25 Oct 2023 Helen Lamb
completed by BSI in Viamed Audit 25th October 23

31 Oct 2023 Derek Lamb Done

Document Control Amendments needed

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241952 11 Nov 2021	Document Update Request (74575) QC 21 Non Conformance	☐	☐	☐	☐	☐	☐	☐

Derek Lamb
Added by Helen Lamb sent to Derek Lamb
Controlled Document (74575) QC 21 Non Conformance Requires Updating Fixed formatting

23 Nov 2021 Derek Lamb
Done

BSI Minor Non conformances
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 / must state in issue if its an observation	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
241898 11 Nov 2021	VIAMED 2128198-202111-N4 QC21	☐	☑	☑	☑	☑	☑	☑

	Form Missing form box ready to send							

Derek Lamb
Added by Derek Lamb sent to Derek Lamb

11 Nov 2021 Derek Lamb
Corrective action process was not fully effective as verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device, didn`t consider by the procedure and template. Non-conformance, Corrective and Preventive Action procedure VOP10, issue 1, ID 46915, 2. 11. 2020, Non-Conformance Report: QC21, Ver. Control 22074, 16. 09. 2017

18 Nov 2021 Derek Lamb

Subject Changed From VIAMED 2128198-202111-N4 QC21 Form Missing form box
Subject Changed To VIAMED 2128198-202111-N4 QC21 Form Missing form box ready to send

09 Dec 2021 Derek Lamb

16 Aug 2022 Helen Lamb
This has now been closed by BSI 16th Aug 22 Nici Lintern-Gittens and Christina GeorgiouDerek and Helen Lamb present Need to review effectiveness

18 Aug 2022 Derek Lambclosure

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 / must state in issue if its an observation	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
16750003 Mar 2020	QC 21 Form Oxygen Sensor - 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

03 Mar 2020 Derek Lamb
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

11 Mar 2020 Derek Lamb
Created Related Issue #168340
Added by Derek Lamb sent to Catrin Hird

09 Apr 2020 Derek Lamb

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

10 Apr 2020 Derek Lamb

BSI Minor Non conformances

Viamed | Vandagraph | VST | Viamed Properties

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		required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / must state in issue if its an observation	its a vigilance Issue requiring a corrective action plan				or regulatory requirements	
155082 24 Sep 2019	1826110-201909-N1	☐	☑	☑	☑	☑	☐	☑

Helen Lamb
Added by Derek Lamb sent to Derek Lamb

24 Sep 2019 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

25 Sep 2019 Helen Lamb
added root cause and corrective action

02 Oct 2019 Helen Lamb
added immediate and corrective actions headings

09 Oct 2019 Derek Lambadded some notes in red

09 Oct 2019 Helen Lamb
reviewed and new version added

09 Oct 2019 Helen Lamb

09 Oct 2019 Derek Lamb Think I`m happy with QC 21 Non Conformance Report 1826110-201909-N1

09 Oct 2019 Helen Lamb
added missing fields inc issue and task ids need checking and see if any other issues and tasks to add NEED TO CHECK

11 Oct 2019 Helen Lamb
final fix

28 Oct 2019 Derek LambBSI acceptance

28 Oct 2019 Derek Lamb
QC28B not required as QMS system not product bases NC

14 Oct 2020 Derek Lamb

ISO - INTRASTATS TODO

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114303 12 Feb 2018	M1 Main QC 21 Non Conformance.doc 1548900-201710-M1	☐	☐	☐	☐	☐	☐	☐

Steve Hardaker
Added by Derek Lamb sent to Derek Lamb

12 Feb 2018 Derek Lamb

Next Action Changed From Derek Lamb To Steve Hardaker See attached files. the BSI report, the major non C starts page 48. and then see our action plans attached. Pretty sure this is the only non conformance they will be interested in closing off. are you in work 21/22/23 of next week? i have to book a day with them, John usually likes Wednesdays so 21st is probably the best day

19 Feb 2018 Steve Hardaker
Im in all week except pm of Tue 20th. Will read through all notes before then.

04 Apr 2019 Steve Hardaker
Closing as per DL. Microstim is being discontinued.

05 Apr 2019 Derek Lamb