VIAMED LTD

Follow-Up Leakage Investigation

Stock Reference 0110051 - Oxygen Sensor T-1

Document status	Follow-up report
Review date	29 July 2026
Supplier	Teledyne Analytical Instruments
Date codes reviewed	B6 and E6
Linked investigation	Supplier Batch Quality Investigation - 0110051 B6

Measure	Result	Comment
Known B6 failures	20 of 118	16.9%
PVM4943 B6 failures	5 of 18	27.8%
Known E6 failures	1 of 2	Small population
New failures found	6 units	5 B6 + 1 E6

Key finding: five B6 sensors that passed the original incoming QA later leaked during repeat testing. One E6 sensor also leaked, so the concern is not demonstrably confined to B6.

1. Purpose of Follow-Up

The original supplier batch quality investigation identified fifteen leaking B6 sensors during incoming QA. As a containment action, the retained B6 sensors that had previously passed were subjected to repeat leakage testing. The two E6 sensors received within PVM4943 were also checked because they formed part of the same mixed receipt.

This report records the repeat-test results, updates the failure position and reassesses the scope of the supplier-quality concern.

2. Repeat Leakage Test Findings

Serial number	Date code	Receipt	Result
338707	B6	PVM4583 - 11 Feb 2026	Leaked
338714	B6	PVM4583 - 11 Feb 2026	Leaked
338718	B6	PVM4583 - 11 Feb 2026	Leaked
338744	B6	PVM4583 - 11 Feb 2026	Leaked
338797	B6	PVM4943 - 6 May 2026	Leaked
360551	E6	PVM4943 - 6 May 2026	Leaked

All five B6 units had passed the original incoming QA inspection. E6 serial 360550 passed the repeat leakage test.

3. Updated B6 Position

B6 status	Quantity
B6 sensors received	118
Original incoming QA failures	15
Additional repeat-test failures	5
Total known B6 failures	20
Revised known B6 failure rate	16.9%
Previously supplied	61
Remaining held and passing repeat test	37

Purchase order	B6 received	Original fails	Recheck fails	Total fails	Rate
PVM4583	100	11	4	15	15.0%
PVM4943	18	4	1	5	27.8%
Total	118	15	5	20	16.9%

4. E6 Position

Only two E6 sensors have ever been received, both within PVM4943. Serial 360551 leaked on repeat test and serial 360550 passed. The observed one-in-two failure proportion cannot support a statistical conclusion, but it shows that the concern is not exclusively limited to B6.

5. Significance of Findings

- Five B6 units passed incoming QA but later leaked, indicating a latent, developing or intermittently detectable defect.
- A single satisfactory leakage test may not provide full assurance that an affected sensor will remain leak-free.
- The E6 failure broadens the possible manufacturing scope beyond date code B6.
- Viamed's repeat-testing containment was effective and prevented six further leaking units from being released.

6. Customer Exposure

Sixty-one B6 sensors were previously supplied to customer accounts CID13568, CID4760 and CID5051. No customer returns or known field failures are recorded in the available IntraStats data. Because retained units passed initially and later leaked, a documented risk-based decision is required regarding monitoring, supplier advice and any proportionate field action.

7. Required Actions

Internal containment

• Segregate the five newly failed B6 sensors and failed E6 serial 360551.

• Add all six units to the linked supplier nonconformance and return records.

• Keep the 37 passing B6 sensors and E6 serial 360550 under controlled hold pending disposition.

• Retain the completed warehouse repeat-test sheet and record the test date, tester and equipment.

Supplier escalation

• Advise Teledyne that the B6 total has increased to 20 of 118 and that five units failed after originally passing.

• Advise that one of two E6 sensors has also leaked.

• Request root cause, affected manufacturing scope, explanation of latent leakage, CAPA, stock disposition advice and guidance concerning the 61 supplied B6 units.

Customer and field review

• Continue active monitoring of complaints and returns for the supplied B6 units.

• Retain barcode, serial, invoice and CID traceability with the issue.

• Complete and document a risk assessment before deciding whether customer communication or other field action is required.

8. Updated Assessment

Finding	Assessment
B6 failure level	20 of 118 known failures (16.9%).
Latent failure	Five units passed initially and failed on repeat test.
Scope	Potentially broader than B6 because one E6 unit failed.
Customer exposure	61 B6 units supplied; no recorded field failures.
Supplier action	Expanded root-cause and scope investigation required.

9. Conclusion

Repeat leakage testing identified five further leaking B6 sensors and one leaking E6 sensor.

The B6 total has increased to twenty failures from 118 sensors, giving a revised known failure rate of 16.9%. The most significant result is that five B6 sensors which passed incoming QA subsequently leaked.

The E6 finding prevents the issue from being treated as exclusively a B6 date-code problem. Viamed's containment action was effective, but the retained stock should remain controlled and the supplier nonconformance should remain open pending root cause, scope confirmation, risk assessment and stock disposition.

10. Updated Classification

Issue type	Supplier nonconformance / incoming and latent product quality failure
Known B6 failures	20 of 118 (16.9%)
Known E6 failures	1 of 2
Known customer field failures	None in available records
Customer exposure	61 B6 sensors - CID13568, CID4760 and CID5051

Status	Open pending supplier response, risk assessment and disposition