SUPPLIER BATCH QUALITY INVESTIGATION

Stock Reference 0110051 - Oxygen Sensor T-1

Manufacturer Date Code B6

Incoming QA failures identified across two receipts. Failures contained before customer supply.

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Prepared for	Viamed Ltd
Supplier	Teledyne Analytical Instruments
Stock reference	0110051
Product	Oxygen Sensor T-1
Date code under review	B6

KEY FIGURES

118	15	12.7%	0
B6 units received	Incoming QA failures	Overall failure rate	Known customer failures

1. Purpose of Investigation

This investigation was triggered when four units of stock reference 0110051 from a receipt of 20 sensors were identified in Supplier Return Box 1090 as having failed Viamed's internal QA testing due to leakage. At the point of initial review, this represented a receipt-level failure rate of **20.0%**, which exceeded Viamed's internal threshold for further investigation.

The initial finding prompted a wider investigation of earlier supplier-return records. This identified Supplier Return Box 1072, containing a further eleven failed units of the same stock reference and manufacturer date code B6. The investigation was therefore expanded to determine whether the four recent failures were isolated items or part of a wider batch-related pattern, and to establish:

- the number of affected units;
- the purchase and receipt history;
- the extent of customer exposure;
- whether Viamed's incoming QA controls operated effectively;
- whether the test equipment used was suitably verified and within its defined calibration cycle;
- the appropriate containment and supplier follow-up actions.

2. Source Information Reviewed

The investigation considered the following internal records:

- Supplier Return Box 1090;
- Supplier Return Box 1072;
- stock reference 0110051 purchasing and receipt history;
- manufacturer date-code return history;
- barcode and serial-number traceability records;
- sales and invoice traceability;
- individual QA results for the February and May 2026 receipts;
- calibrated equipment records for DVM CE111;
- verification records showing CE111 tested against calibrated MicroCal reference equipment CE076.

3. Initial Trigger

Supplier Return Box 1090 contained four units of stock reference 0110051 recorded as:

> *Leaking — Failed in QA — Did not reach end user.*

Barcode	Serial number	Date code	Receipt date	Return box
2957403	338794	B6	6 May 2026	1090
2957404	338795	B6	6 May 2026	1090
2957407	338798	B6	6 May 2026	1090
2957408	338799	B6	6 May 2026	1090

All four units were detected internally and were not supplied to a customer. As the May receipt contained 20 sensors, the four failures initially represented a **20.0% receipt-level failure rate**, exceeding Viamed's internal investigation threshold.

This triggered the wider traceability investigation, which identified a further eleven failed units from the same B6 date code in Supplier Return Box 1072. Subsequent batch reconciliation established that only 18 of the 20 sensors in the May receipt carried date code B6, giving a B6-specific failure rate of **22.2%** for that receipt.

4. Receipt and Batch Reconciliation

The B6 population was received across two Viamed purchase receipts.

Purchase order	Receipt date	Total received	B6 units	Other date code	B6 failures	B6 failure rate
PVM4583	11 February 2026	100	100	0	11	11.0%
PVM4943	6 May 2026	20	18	2 × E6	4	22.2%
Total		**120**	**118**	**2 × E6**	**15**	**12.7%**

The earlier apparent discrepancy between 118 and 120 units is therefore explained. The May receipt contained 20 sensors in total, but only 18 carried date code B6. The remaining two sensors carried date code E6.

The correct B6 denominator is therefore **118 units**.

5. Failed B6 Units

The fifteen failed units were distributed across the B6 serial-number range rather than being confined to a single uninterrupted sequence.

Return box	Serial numbers
1072	338698, 338701, 338716, 338723, 338739, 338740, 338752, 338772, 338776, 338784, 338790
1090	338794, 338795, 338798, 338799

The failures occurred from serial 338698 through to serial 338799.

Although there are small local clusters, particularly within the later receipt, the failures are spread across much of the production sequence. This makes a single isolated carton, one short handling event or one individual serial group less likely as the sole explanation.

6. Current Stock and Traceability Position

February receipt — PVM4583

- 100 B6 units received;
- 61 booked out;
- 39 still shown within the batch trace;
- 11 of the 39 are failed units held in Box 1072;
- 28 passing B6 units therefore appear to remain held.

May receipt — PVM4943

- 20 total units received;
- 18 were B6;
- 2 were E6;
- no units were booked out;
- 4 B6 units are held in Box 1090;
- 14 passing B6 units therefore appear to remain held;
- both E6 units passed QA and remain held.

Reconciled B6 position

Status	Quantity
B6 units supplied/booked out	61
Passing B6 units still held	42
Failed B6 units held for supplier return	15
Total B6 units	**118**

The IntraStats “Still in Stock” or “Left” figure includes items that have been assigned to supplier-return boxes. It is therefore a batch-balance figure and should not be interpreted automatically as available usable stock.

7. Customer Exposure

The fifteen failed units did not reach customers.

However, 61 other B6 units passed Viamed QA and were subsequently supplied to three customers:

- CID13568;
- CID4760;
- CID5051.

The available traceability data shows no customer return recorded against those 61 supplied B6 units.

The correct statement is therefore:

> *Fifteen B6 units failed Viamed's incoming QA and were prevented from reaching customers. Sixty-one other B6 units passed QA and were supplied, with no customer returns identified in the available data.*

No evidence has been identified within the reviewed records of a customer complaint, field failure, patient incident or product recall associated with the supplied B6 units.

8. QA Inspection Results

The records show that every unit from both receipts was individually tested rather than inspected by sampling.

February receipt

- 100 units tested;
- 89 passed;
- 11 failed;
- all 11 failed serials correspond with the units held in Box 1072.

May receipt

- 20 units tested;
- 16 passed;
- 4 failed;
- all 4 failed serials correspond with the units held in Box 1090;
- the two E6 units passed.

The QA records therefore align with the return-box records and the batch traceability records.

This confirms that Viamed's incoming QA process successfully identified and contained the failed units before supply.

9. Test Conditions

The QA records include temperature and atmospheric pressure values.

February testing

- temperature approximately 16.8°C to 18.6°C;
- atmospheric pressure approximately 97,621 Pa to 98,002 Pa.

May testing

- temperature approximately 17.6°C to 21.5°C;
- atmospheric pressure approximately 100,246 Pa to 100,417 Pa.

Passing and failing units were recorded under the same or very similar environmental conditions. No clear relationship is evident between the recorded temperature or atmospheric pressure and the failures.

Humidity is recorded as 0.00 throughout. This appears to be an unused, unrecorded or non-integrated data field and should not be interpreted as a genuine zero-humidity measurement.

10. Test Equipment and Verification Status

The QA testing used:

- **Equipment:** Caltek CM1200A DVM;
- **Viamed equipment reference:** CE111;
- **Barcode:** 102095;
- **verification date:** October 2024;
- **next due date:** October 2026;
- **status:** Calibrated / verified within Viamed's defined two-year cycle.

Viamed verifies its DVM equipment against calibrated reference equipment on a two-year cycle.

CE111 was checked on 16 October 2024 against:

- **Reference equipment:** MicroCal 1030;
- **reference equipment number:** CE076;
- **barcode:** 102060;
- **serial number:** 6939K6;
- **calibration certificate:** BTM 12439.

The verification sheet records applied values from 0 mV to 40 mV and corresponding DVM readings. CE111 passed the check and remained within its defined verification period during both the February and May 2026 QA inspections.

There is therefore no evidence that the fifteen failures were caused by an overdue, unverified or inaccurate DVM.

11. Historical Context

The supplier-return history for stock reference 0110051 includes returns from a range of earlier manufacturer date codes. However, the B6 data differs in several important respects:

- the failures were identified immediately through Viamed QA rather than after extended customer use;
- fifteen failures occurred within a relatively recent population of 118 units;
- failures occurred across two separate Viamed receipts carrying the same manufacturer date code;
- the combined B6 incoming failure rate is 12.7%;
- the later B6 receipt had an incoming failure rate of 22.2%.

Historic return counts cannot be compared directly without considering the length of time in service and whether the earlier returns were customer failures, no-fault-found returns, warranty claims or internal QA failures. Nevertheless, the B6 pattern is sufficiently concentrated and immediate to justify formal supplier escalation.

12. Assessment

The evidence supports the following assessment:

1. **The failures are associated with manufacturer date code B6.**
   Fifteen units from the B6 population failed incoming QA across two separate Viamed receipts.
2. **The issue is unlikely to be confined to one isolated receipt or one carton.**
   Both the February and May receipts contained failed B6 units.
3. **The failures are not explained by an obvious environmental testing condition.**
   Passing and failing units were tested under similar recorded temperature and pressure conditions.
4. **The test equipment was suitably controlled.**
   CE111 had passed verification against calibrated reference equipment and was within its defined two-year verification cycle.
5. **Viamed's incoming QA control was effective.**
   All fifteen failed units were identified and contained before they reached customers.
6. **There has been customer exposure to other B6 units, but no identified field failure.**
   Sixty-one B6 units passed QA and were supplied. No customer return is shown for those units in the available records.
7. **A supplier manufacturing, sealing, material or batch-process issue remains the most credible explanation.**
   The available data does not establish the root cause, which requires Teledyne investigation.

13. Recommended Actions

Immediate containment

- Retain the fifteen failed B6 units in controlled supplier-return locations.
- Clearly identify the 42 passing B6 units still held.
- Prevent release of the remaining B6 stock until management confirms the required containment approach.
- Reconcile the physical stock against the barcode-level trace to confirm all 118 B6 units are accounted for.

Internal review

- Confirm whether the 42 passing units should undergo repeat leak testing before release.
- Retain the individual QA results and equipment-verification evidence with the investigation.
- Link Boxes 1072 and 1090 to one supplier-quality issue.
- Confirm that the fault description for all fifteen failed units is consistently recorded as leakage.

Supplier escalation

Provide Teledyne with:

- both purchase-order references;
- both receipt dates;
- the full list of fifteen failed serial numbers and barcodes;
- the 12.7% combined B6 incoming failure rate;
- confirmation that the failures occurred across two receipts;
- confirmation that all units were individually QA tested;
- confirmation that the test equipment was within its verification cycle.

Request from Teledyne:

- a formal root-cause investigation;
- confirmation of the full affected manufacturing range;
- confirmation whether date code B6 represents one manufacturing batch or a wider production period;
- advice on the reliability of B6 units that currently pass Viamed QA;
- corrective and preventive action information;
- replacement or credit for the failed units;

- any recommended action for units already supplied or still held.

Customer review

- Continue to monitor complaints and returns for the 61 supplied B6 units.
- Retain the customer and invoice traceability list with the investigation.
- Do not initiate customer contact, field action or recall solely on the present evidence unless the supplier investigation, further internal failures or customer feedback indicates that additional action is necessary.

14. Conclusion

The investigation identified a clear concentration of incoming QA failures affecting stock reference 0110051 with manufacturer date code B6.

A total of 118 B6 sensors were received across two purchase receipts. Fifteen failed Viamed's incoming QA, giving an overall failure rate of 12.7%. The failures occurred across both receipts and across a broad serial-number range.

Viamed's controls operated effectively. Every unit was individually tested, the failed units were identified before supply, and the test equipment was within its defined verification cycle. There is no evidence within the reviewed data that the failures were caused by Viamed's test equipment or by the recorded environmental test conditions.

Sixty-one B6 units passed QA and were supplied to customers. No customer returns or field failures have been identified in the available records. Forty-two passing B6 units remain held, together with fifteen failed units awaiting supplier action.

The evidence is sufficient to raise and maintain a formal supplier nonconformance and request a documented Teledyne root-cause investigation. The issue should remain open until the remaining stock position has been confirmed, the containment decision has been documented, and Teledyne has provided a satisfactory response regarding root cause, affected scope and corrective action.

15. Proposed Classification

Issue type: Supplier nonconformance / incoming product quality failure **Current impact:** Internally contained **Customer complaints identified:** None **Known customer field failures:** None **Immediate safety incident identified:** None **Supplier escalation required:** Yes **Further internal containment decision required:** Yes **Issue status:** Remain open pending supplier response and stock disposition

Approval and Closure

Reviewed by	
Role	
Date	
Decision	Open / Closed / Further action required