

MANAGEMENT REVIEW VST 18 Oct 2017

a. Follow-up actions from previous reviews

No followup actions in last review

b. Customer feedback

No negative feedback,

c. Results of internal audits / Mini Audits

Agree to continue with current audit plan, alterations are due, but mainly additions due to the viamed rolling audits.

d. Process and product performance.

Product performance is excellent very low returns rate, non issues with getting the goods to the customers, debtors are good, no over due debtors (aside from the erroneous 30.17)

VST oxygen sensors cross reference performance data 2017-10-18

In summary:

Sensors sold to date: 83,529

Total number of returns: 759 (0.90%)

Total number of *faulty sensors: 509 (0.61%)

Total number of sensors - no fault found: 249 (0.29)

NOTE: Historically we included all sensors, whether in or out of warranty.

Many sensors far exceeded warranty period, so we are now indicating them as: Out of warranty. This is in order to provide a true reflection, as some sensors were just consumed through usage and not faulty.

8010012 We had a batch failure and Megalodon do return a good number of sensors, many are out of warranty, which we have been replacing as a good will gesture. The underlying performance of the sensor is very good. During 2017 it has successfully passed rigorous performance evaluation testing by the US Navy (NEDU).

8010010 The figure of 6.54% stands out. This is due to use/mishandling of the sensor and partly due to the design of the sensor holder assembly in the rebreather. The sensors are also subject to high temperature and high humidity environments. We have employed design changes to minimize this and sensors are currently in the field for long-term storage and performance evaluations.

Currently we are seeking approval from the OEMs to implement a revised membrane assembly. This will improve production and also offers improved long-term performance, especially in regard to evaporation of electrolyte and absorption of humidity.

See spreadsheet against Issue 105722

See attached: VST annual sales figures 2010 to 2017

Sales figures are encouraging and from the latest accounts profitability is good.

Revision of procedures during 2017 has significantly reduced QA processing time by Viamed personnel.

Sales to the US Navy have started via InnerSpace.

Assuming that they pass the performance testing, we anticipate releasing two new non-mage sensors for military applications. These could prove to be very profitable and also raise the profile of VST and our capabilities.

Shearwater have a development project with Analytical Industries regarding a smart sensor. The performance and acceptance of this in the market could have a significant effect, it go either negatively or positive for us.

VST future developments include:

a) Diamagnetic anode.

b) Cathodes using different materials (i.e. platinum), this will provide improved linearity performance at higher ppO2 levels. The expiry of the Teledyne patent has enable this.

c) Lead-free sensor..

See Issue 105743

e. Preventive and corrective actions.

f. Possible system changes.

Updating the ISO, some extra reports may be needed, being addressed with the viamed tasks and audits updates

g. Recommendations or improvement

discussed but overall happy with the current system

h. Any other business

non

1. Contract review / Picking, Packing & Despatch
No issues found in the processing of the products
2. Purchasing controls
Director signs most orders, and only utilising 2 suppliers (Viamed and envitec)
3. Supplier / subcontractor performance
current year approx 0.006% return rate 128 sensors out of 20620
4. Storage & Stock control
Stock is not held on site, using JIT ordering and shipping. Barcode tracking working as per viamed system. No issues for concern
5. Customer complaints
Single Customer Complaint CCR151 no details yet.– also checked Viamed header in case of misspost of issue
6. Calibration
As per Viamed System. Although limited testing done in house, only required for sensor returns prior to shipping back to main manufacturer for further investigation
7. Documentation & records
Most records controlled via intrastats, Envitec QA results data, stored on Z drive as they are received with shipments rolling issue to upload to VST technical file as on mass zip file adequate for now.
8. Training
Limited training required, as not internally manufactured, Normal office training and warehouse training in line with Viamed training is adequate
9. Review of responsibilities
Reviewed in the Viamed Management review in regards to viamed, agree no changes required for VST
10. Resources required
Viamed resources covering current requirements
11. New products etc.

12. Quality planning

13. Quality Policy

Quality policy updated in line with newer standards (9001:2015)

14. Advisory notices & recalls

No Recalls.

15. Vigilance system

Happy with the current monitoring of product and product returns

17. Changes to the Management system

Upgrading to 9001:2015, addition of the roles and titles (via the viamed system) and rolling tasks and audits.

18. Changes to CE marked products

Does not strictly apply as it does with VIamed

In Attendance

Derek Lamb

John Lamb

Steve Nixon