



VIA MED

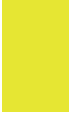
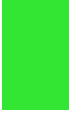
Vandagraph VST Sensors

NBOG MD 0101

Carried out by Derek Lamb
13 / 05 / 14



VIA MED

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Stock References Review

Stock Reference	Description
8000004	Cable assembly for oxygen sensor 8010004
8010000	Oxygen Sensor - VST2200
8010001	Oxygen Sensor - APD5
8010002	Oxygen Sensor - APD11
8010002	Oxygen Sensor - APD11
8010003	Oxygen Sensor - VR1700
8010004	Oxygen Sensor - R17JJ-CCR
8010005	Oxygen Sensor - VST1700
8010006	Oxygen Sensor - rEvo CR22D
8010006	Oxygen Sensor - rEvo CR22D
8010007	Oxygen Sensor - NaNS01
8010007	Oxygen Sensor - NaNS01
8010008	Oxygen Sensor - NaNM01
8010008	Oxygen Sensor - NaNM01
8010009	Oxygen Sensor - VST1200
8010009	Oxygen Sensor - VST1200
8010010	Oxygen Sensor - RBL-23D
8010011	Oxygen Sensor - VR2200
8010011	Oxygen Sensor - VR2200
8010012	Oxygen Sensor - SC-I22D
8010012	Oxygen Sensor - SC-I22D
8010014	Oxygen Sensor - K-22D
8010015	Oxygen Sensor - UDT-22
8010016	Oxygen Sensor - Hammerhead HH22
8010017	Oxygen Sensor - VMS1700
8010018	Oxygen Sensor - Triton T22D
8010022	Oxygen Sensor - APD16

Comments on Stock references review:

All numbers are correct,

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
8010000	Oxygen Sensor - VST2200	00007282	EnviteC-Wismar GmbH	A
8010001	Oxygen Sensor - APD5	00007282	EnviteC-Wismar GmbH	A
8010002	Oxygen Sensor - APD11	00007282	EnviteC-Wismar GmbH	A
8010003	Oxygen Sensor - VR1700	00007282	EnviteC-Wismar GmbH	A
8010004	Oxygen Sensor - R17JJ-CCR	00007282	EnviteC-Wismar GmbH	A
8010006	Oxygen Sensor - rEvo CR22D	00007282	EnviteC-Wismar GmbH	A
8010007	Oxygen Sensor - NaNS01	00007282	EnviteC-Wismar GmbH	A
8010008	Oxygen Sensor - NaNM01	00007282	EnviteC-Wismar GmbH	A
8010010	Oxygen Sensor - RBL-23D	00007282	EnviteC-Wismar GmbH	A
8010012	Oxygen Sensor - SC-I22D	00007282	EnviteC-Wismar GmbH	A
8010014	Oxygen Sensor - K-22D	00007282	EnviteC-Wismar GmbH	A
8010016	Oxygen Sensor - Hammerhead HH22	00007282	EnviteC-Wismar GmbH	A
8010017	Oxygen Sensor - VMS1700	00007282	EnviteC-Wismar GmbH	A
8010018	Oxygen Sensor - Triton T22D	00007282	EnviteC-Wismar GmbH	A
8010022	Oxygen Sensor - APD16	00007282	EnviteC-Wismar GmbH	A
8000004	Cable assembly for oxygen sensor 8010004	0009192		Needs Grading

Comments on Suppliers:

Supplier error 0009192.

Cables made by Viamed, need to see why pc not letting me rate the supplier.

Follow up Issue #50261

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
8000004	Cable assembly for oxygen sensor 8010004				905	2260	3532	1800
8010000	Oxygen Sensor - VST2200				79	123	20	21
8010001	Oxygen Sensor - APD5					2		
8010002	Oxygen Sensor - APD11				3			
8010002	Oxygen Sensor - APD11				3			
8010003	Oxygen Sensor - VR1700				707	726	642	130
8010004	Oxygen Sensor - R17JJ-CCR				797	1103	1648	750
8010005	Oxygen Sensor - VST1700							
8010006	Oxygen Sensor - rEvo CR22D				501	1910	2100	750
8010006	Oxygen Sensor - rEvo CR22D				501	1910	2100	750
8010007	Oxygen Sensor - NaNS01				558	751	1600	800
8010007	Oxygen Sensor - NaNS01				558	751	1600	800
8010008	Oxygen Sensor - NaNM01				30	450	1000	300
8010008	Oxygen Sensor - NaNM01				30	450	1000	300
8010009	Oxygen Sensor - VST1200							
8010009	Oxygen Sensor - VST1200							
8010010	Oxygen Sensor - RBL-23D					138	100	
8010011	Oxygen Sensor - VR2200				3			
8010011	Oxygen Sensor - VR2200				3			
8010012	Oxygen Sensor - SC-I22D				249	1900	1787	700
8010012	Oxygen Sensor - SC-I22D				249	1900	1787	700
8010014	Oxygen Sensor - K-22D					54	180	120
8010015	Oxygen Sensor - UDT-22							
8010016	Oxygen Sensor - Hammerhead HH22						301	100
8010017	Oxygen Sensor - VMS1700							130
8010018	Oxygen Sensor - Triton T22D							50
8010022	Oxygen Sensor - APD16							500

Comments on Sales Information:

Sales are increasing

Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
					[X]		
AU Austria					[X]		
B Belgium				[X]	[X]	[X]	[X]
CZ Czech Republic				[X]	[X]	[X]	
DE Denmark				[X]	[X]	[X]	[X]
F France							[X]
G Germany				[X]	[X]	[X]	[X]
HA HAWAII					[X]		
IT Italy					[X]		
SW Sweden				[X]	[X]		
TH Thailand				[X]	[X]	[X]	
UK United Kingdom				[X]	[X]	[X]	[X]
USA U.S.A.				[X]	[X]	[X]	[X]

Comments on Sales to Countries:

no comment

Comments on Risks with Sales to Countries:

Returns Review

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
8010000	No Fault Found					3		
8010003	Connector - corrosion						2	3
8010003	Low output during dive				1			
8010003	No Fault Found							8
8010003	No output							2
8010004	Cable connections faulty							1
8010004	High output							1
8010004	No Fault Found				3		2	3
8010004	No output							1
8010004	Unstable output signal							1
8010004	Zero offset signal out of tolerance							1
8010006	Conformal coating on connector				2			
8010006	Low Output					1		
8010006	No Fault Found				1	1		
8010006	No output							1
8010006	Unstable				1			
8010006	Zero offset out of tolerance							1
8010007	Linearity error						1	
8010007	Low output							1
8010007	No Fault Found						2	8
8010007	No output							2
8010007	Unstable output signal						1	1
8010007	Zero offset signal out of tolerance							2
8010008	Electrolyte leakage						1	
8010008	No fault found							1
8010008	No output						2	
8010008	Unstable output signal						1	
8010008	Zero offset signal out of tolerance							2
8010010	Zero offset signal out of tolerance							8
8010012	High output						1	
8010012	Linearity error						12	
8010012	Low output						3	
8010012	No Fault Found						2	1
8010012	No output					1	1	1
8010012	Unstable output signal						3	
8010012	Zero offset signal out of tolerance							23
8010014	Low output							1
8010014	Zero offset signal out of tolerance							1
8010016	Output cap unattached							1

Comments on Returns:

generally returns are very very low,

aside from part number 8010010:

Spoken to SN regarding this number:

Customers Megalodon and Innerspace:

returns are isolated to Megalodon only,

3 possible reasons

a/ 94 Sensors were Overtested, but through a major stress test.

b/ testing procedure damaging the sensor

c/ Megalodon might be trying to recoup perceived failures.

SN is carrying out an on site visit to both inner space and megalodon to observe the testing procedures and discuss.

No further action required at this stage

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Comments on User Instructions:

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9501	Vandagraph VST Sensors Labels	18/10/11

Comments on Labels:

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

Document system being brought into line with the Viamed system,
all documents at this stage appear to be new,

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 74

Issue ID	Subject
49125	VST 8010003 stock relabelling
48106	Free issue parts stock at Envitec
48018	8000004 oxygen sensor cables
47381	8010007 stock
33291	VST oxygen sensor QA test data - Envitec
32558	Stock location for 80xxxxx series parts
32557	Stock location for 80xxxxx series parts
32556	Stock location for 80xxxxx series parts
32179	Potting resin - 8000004 cable assemblies
32178	Potting resin - 8000004 cable assemblies
30719	Bar codes 8010003
30718	Bar codes 8010007
29918	QA Form needed
29652	VST stock conversion
26771	VST sensors 8010004 110111
26770	VST sensors 8010004 110111
26769	VST sensors 8010004 110111
49503	DOCID 13653
29786	Document/Picture (DOCID8535) Update Request
34313	Batch Pass Products
28292	VST stock quantities
28106	VST stock conversion
28088	VST Opera issue
28013	Message
27808	Covertsion of 9 x 8010001 into 8010000
27570	8000004 for stock
46690	PMS Viamed OBL product Envitec Oxygen Sensors Stock References
39742	PMS Viamed OBL product Envitec Oxygen Sensors Sales Countries
48612	VST returns Count type field
48373	0150040 factory stock count
43105	8010012 Packaging issue
40824	VST stock error ref. 8000004
30168	Narked at 90 order
30167	Narked at 90 order
30166	Narked at 90 order
30165	Narked at 90 order
25064	R17JJ-CCR labelling query
25063	R17JJ-CCR labelling query
25062	R17JJ-CCR labelling query
48899	APD
44741	Part number 8010012
44740	Part number 8010012

Issue ID	Subject
44359	VST first 10,000 sensors - returns data
49255	Active sales - Uncharted Diving Technology
49254	Active sales - Poseidon
49248	Active sales - Halcyon
49246	Active sales - Divesoft
49242	Active sales - American Underwater Products
49241	Active sales - Alvin Diving Centre, Mentos
50243	Narked at 90 delivery schedule
50242	Narked at 90 delivery schedule
50241	Narked at 90 delivery schedule
50240	Narked at 90 delivery schedule
50239	Narked at 90 delivery schedule
50238	Narked at 90 delivery schedule
49321	VST purchase orders
49302	8010004 stock levels
38750	VST P.O. edit VSTPO00003
49405	8030498 Quotation
48848	150 x 8010006
48835	8010004
48016	VST sensor order
47782	8010007 & 8010008
47603	Purchase order for 8010003
46902	VST - 8010004
46901	VST - 8010004
48752	Stock adjustments - 11/03/14
48751	Stock adjustments - 11/03/14
48535	VST sales order to Envitec
39636	VST - Application of Narked at 90 oxygen sensors
39635	VST - Application of Narked at 90 oxygen sensors
39634	VST - Application of Narked at 90 oxygen sensors
39633	VST - Application of Narked at 90 oxygen sensors
33340	VST 8010010 RBL-23D

Comments on Issues:

no major problems found in the Issues system,
lots of Issues as first time run on PMS system.

Comments on Risks with Issues:

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem :
Do any of the Results indicate outdated Technology :
Comments on Clinical Search :

NOT APPLICABLE to VST

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem :
Do any of the Results indicate outdated Technology :
Comments on Clinical Search :

NOT APPLICABLE to VST

Risk ISO 14971 : 2012 Review

Full ISO 14971 : 2012 Risk review held off-site at original OEM company