



VIA MED

Envitec Oxygen Sensors

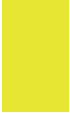
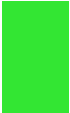
A medical device for measuring the proportion of oxygen in respiration gases.

Class IIa
Via Rule 10
Assesment Route Annex II

Carried out by Derek Lamb
20 / 04 / 16



VIA MED

-  Stock References Review
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-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

Stock References Review

Stock Reference	Description
0110021	Oxygen sensor R-22MEDV
0110023	Oxygen sensor R-23V
0110040	Oxygen sensor R-30V
0110041	Oxygen sensor R-41V
0110042	Oxygen sensor R-42V
0110043	Oxygen sensor R-43V. Pack of 2 sensors.
0110044	Oxygen sensor R-44V
0110045	Oxygen sensor R-45V
0110046	Oxygen sensor R-46V
0110047	Oxygen sensor R-47V
0110048	Oxygen sensor R-48V
0110049	Oxygen sensor R-49V
0110071	Oxygen sensor R-22MEDV. Pack of 2
0111275	Oxygen analyser OxiQuant S
0120090	Oxygen sensor O ring.
0120091	Oxygen sensor O ring for R-30V
0120092	Oxygen sensor flow diverter 15 mm.
0120095	Oxygen sensor flow diverter 15 mm.
0120096	Oxygen sensor flow diverter O ring 18mm
0120097	Oxygen sensor flow diverter 18 mm.
0120098	Oxygen sensor flow diverter O ring 15mm
0120099	Oxygen sensor flow diverter 15mm.

Comments on Stock references review:

added 0111275, but were not actually selling it currently
added 0120090 and 0120091
also added the flow sensors for the report

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0110021	Oxygen sensor R-22MEDV	00007282	01-00-0015	EnviteC-Wismar GmbH	A
0110023	Oxygen sensor R-23V	00007282	01-00-0014	EnviteC-Wismar GmbH	A
0110040	Oxygen sensor R-30V	00007282	01-00-0098	EnviteC-Wismar GmbH	A
0110041	Oxygen sensor R-41V	00007282	01-00-0021	EnviteC-Wismar GmbH	A
0110042	Oxygen sensor R-42V	00007282	1000106	EnviteC-Wismar GmbH	A
0110043	Oxygen sensor R-43V. Pa	00007282	1001202	EnviteC-Wismar GmbH	A
0110044	Oxygen sensor R-44V	00007282	01-00-0068	EnviteC-Wismar GmbH	A
0110045	Oxygen sensor R-45V	00007282	01-00-0091	EnviteC-Wismar GmbH	A
0110047	Oxygen sensor R-47V	00007282	01-00-0097	EnviteC-Wismar GmbH	A
0110048	Oxygen sensor R-48V	00007282	1002178	EnviteC-Wismar GmbH	A
0110049	Oxygen sensor R-49V	00007282	01-00-0047	EnviteC-Wismar GmbH	A
0111275	Oxygen analyser OxiQuant	00007282	46-00-0021	EnviteC-Wismar GmbH	A
0120091	Oxygen sensor O ring for	00007282	1001335	EnviteC-Wismar GmbH	A
0120092	Oxygen sensor flow diver	00007282	01-002173	EnviteC-Wismar GmbH	A
0110021	Oxygen sensor R-22MEDV	00009147	01-00-0015	Teledyne Analytical Inst	A
0110023	Oxygen sensor R-23V	00009147	01-00-0014	Teledyne Analytical Inst	A
0120096	Oxygen sensor flow diver	00011712	RP56P03-002	Maxtec Inc.	B
0120097	Oxygen sensor flow diver	00011712	RP33P42-002	Maxtec Inc.	B

Comments on Suppliers:

supplier review upto date,
error in report showing teledyne as they were the old supplier (or alternative supplier a few years ago)

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0110021	Oxygen sensor R-22MEDV		48	27	49	1339	1740	473
0110023	Oxygen sensor R-23V	1482	1756	1226	1432	1930	1891	578
0110040	Oxygen sensor R-30V	110	342	267	340	495	554	132
0110041	Oxygen sensor R-41V	10	15	19	70	116	101	34
0110042	Oxygen sensor R-42V	4	37	35	87	89	33	13
0110043	Oxygen sensor R-43V. Pa	95	365	216	234	310	270	80
0110044	Oxygen sensor R-44V		15	4	6	12	8	2
0110045	Oxygen sensor R-45V	5	13		2	78	80	3
0110046	Oxygen sensor R-46V							
0110047	Oxygen sensor R-47V		56	64	161	304	363	129
0110048	Oxygen sensor R-48V						40	12
0110049	Oxygen sensor R-49V					2	101	55
0110071	Oxygen sensor R-22MEDV. Pack of 2		328	300	494	490	642	152
0111275	Oxygen analyser OxiQuant						5	
0120090	Oxygen sensor O ring.		40	20	20	11	10	
0120091	Oxygen sensor O ring for				20			
0120092	Oxygen sensor flow diver							30
0120095	Oxygen sensor flow diverter 15 mm.							
0120096	Oxygen sensor flow diver						1	
0120097	Oxygen sensor flow diver						1	
0120098	Oxygen sensor flow diverter O ring 15mm			92	50	6	30	30
0120099	Oxygen sensor flow diverter 15mm.	330	121	86	110	70	30	32

Comments on Sales Information:

units still selling

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
AL Algeria		[X]					
ALB Albania			[X]	[X]			
AU Austria							
B Belgium		[X]	[X]				
BA State of Bahrain			[X]		[X]		
BRA Brazil		[X]			[X]	[X]	
BU Bulgaria	[X]	[X]	[X]	[X]	[X]	[X]	[X]
C China	[X]	[X]		[X]	[X]	[X]	[X]
CAM CAMBODIA						[X]	
CH Chile							
CY Cyprus			[X]				
CZ Czech Republic				[X]	[X]	[X]	[X]
DE Denmark	[X]	[X]	[X]				[X]
EG Egypt		[X]					
ES Estonia					[X]		
F France			[X]	[X]	[X]	[X]	[X]
FI Finland							
G Germany		[X]		[X]		[X]	
GEO Georgia		[X]					
GR Greece	[X]	[X]	[X]	[X]	[X]	[X]	[X]
HU Hungary				[X]	[X]		
I Iran						[X]	
IN India	[X]	[X]		[X]	[X]	[X]	[X]
IRE Ireland	[X]	[X]	[X]	[X]	[X]	[X]	
IS Israel		[X]	[X]	[X]	[X]	[X]	[X]
IT Italy	[X]	[X]	[X]				
J Japan	[X]						
JO Jordan			[X]			[X]	
KE Kenya				[X]	[X]	[X]	
KU Kuwait							
LA Latvia	[X]		[X]	[X]	[X]	[X]	
LEB Lebanon	[X]	[X]	[X]	[X]	[X]	[X]	
LI Lithuania		[X]	[X]	[X]	[X]	[X]	[X]
LIB Libya			[X]		[X]	[X]	[X]
MA Malaysia		[X]	[X]	[X]	[X]	[X]	[X]
MAC Macedonia				[X]			
MO Morrocco	[X]	[X]	[X]	[X]	[X]	[X]	[X]
NE Netherlands				[X]			
NEP Nepal			[X]				
NG Nigera			[X]				
NO Norway							
OM Oman		[X]				[X]	

Country	2010	2011	2012	2013	2014	2015	2016
P Poland		[X]	[X]	[X]	[X]	[X]	[X]
PA Pakistan						[X]	[X]
PAL Palestine					[X]		
PH Philippines		[X]		[X]	[X]	[X]	
PO Portugal				[X]	[X]	[X]	[X]
Q Qatar					[X]		
RO Romania	[X]		[X]	[X]	[X]	[X]	[X]
SA South Africa	[X]	[X]		[X]	[X]		
SAU Saudi Arabia		[X]	[X]	[X]	[X]		
SER Serbia	[X]	[X]	[X]	[X]	[X]	[X]	[X]
SI Singapore			[X]				
SL Slovenia			[X]	[X]	[X]	[X]	
SP Spain	[X]			[X]	[X]	[X]	[X]
SRI Sri Lanka		[X]				[X]	
SW Sweden							
SWI Switzerland		[X]					
SY Syria							
T Turkey	[X]	[X]					
TH Thailand	[X]						
UAE U A E	[X]	[X]		[X]	[X]	[X]	[X]
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA	[X]						
VE Venezuela				[X]			
VI Vietnam			[X]	[X]			

Comments on Sales to Countries:

Iran showing as error, was due to a invoicing error in the delivery note,
the old accounts package logged it incorrectly, but still reflect in the reports even tho it was credited

Comments on Risks with Sales to Countries:

no risk identified with countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0110021	No Fault Found			1			2	
0110021	No output						2	
0110021	Unchecked - Returned to Stock							
0110021	Unstable			1			1	
0110023	Bubble in electrolyte			2	3	10	7	1
0110023	Calibration failed				1	1	1	
0110023	Case fault						1	
0110023	Electrolyte leakage						1	
0110023	Fluctuating o/p - During Use		1	2				
0110023	High output - During Use							
0110023	High output - will not calibrate		1				2	
0110023	Leaked - During Use				1	1	1	
0110023	Low Output						1	
0110023	Low output - During Use							
0110023	No Fault Found	2	1					
0110023	No Fault Return to Stock							
0110023	No output	2				1		
0110023	No output - During Use							
0110023	Non Linear - During Use							
0110023	Offset failure	1						
0110023	Rising output - During Use							
0110023	Tarnished input ring						9	
0110023	Unchecked - Returned to Stock							
0110023	Unstable			1		2		
0110023	Will not Calibrate - During Use							
0110040	Fluctuating o/p - During Use			1				
0110040	High output - will not calibrate				1			
0110040	Low Output				2			
0110040	No Fault Found		2	1	1			
0110040	Will not Calibrate - During Use				1			
0110041	Low Output				1			
0110041	Unstable				1			
0110042	Cable fault			3				
0110042	Unchecked - Returned to Stock							
0110043	Bubble in electrolyte			2	7	2		
0110043	Calibration failed							4
0110043	End of life			3				
0110043	Low Output		1			6		
0110043	No Fault Found					1		
0110043	Unchecked - Returned to Stock							
0110043	Unstable				1			
0110044	Unchecked - Returned to Stock							

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0110045	Calibration failed			1			1	
0110045	Low Output					1		
0110045	No output					2		
0110047	Calibration failed			3			1	
0110047	Fluctuating o/p - During Use			1			1	
0110047	No Fault Found						1	
0110071	Both cells faulty				2	1		
0110071	Calibration failed			4	5	1	6	9
0110071	Case fault							1
0110071	Fluctuating o/p - During Use					1		
0110071	High output - will not calibrate			3				
0110071	Low Output			1	1	2	16	
0110071	No Fault Found			5	3	1	3	
0110071	No output					1		
0110071	Not a matched pair			1	2	1	8	
0110071	Offset failure						1	
0110071	Unchecked - Returned to Stock							
0110071	Unstable				1	2	1	

Comments on Returns:

very limited number of returns, within the expected failure of the devices

Comments on Risks with Returns and Potential Re-work:

no risks identified with returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Inner cell changed.

Comments on Risks with Design Changes:

no risks identified with design changes

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
16693	Instructions for Use - Viamed Medical Oxygen Sensors	29/03/16
15467	Vandagraph VST Sensors Instructions for Use User Manual	14/08/15
9166	NO user instructions required	18/10/11

Comments on User Instructions:

IFUs for all oxygen sensors are currently under review, all suppliers have a different interpretation of requirements, and weather the product is a component, or a device in its selfs

Comments on Risks User Instructions:

no risks with the ifu`s alothough they are under discussion accross the different suppliers of similar products

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15743	Envitec Oxygen Sensors viamed Labels	29/09/15
9169	No accessory labels	18/10/11

Comments on Labels:

Labels still fit for purpose,
there are discussions under way regard the use of the blue man symbol, is the device a device or a
component is the area of question

Comments on Risks Labels:

no risks identified with the IFU

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16789	Declaration of Conformity Viamed Oxygen Sensors	20/04/16
16701	Envitec Oxygen Sensor Quality Assurance agreement Appendix 1	01/04/16
16700	Envitec Oxygen Sensor Quality Assurance agreement	01/04/16
16693	Instructions for Use - Viamed Medical Oxygen Sensors	29/03/16
16320	0110021 Specification Datasheet	17/02/16
15900	Viamed ISO CE Certificate Private Labelling Envitec 97289	06/11/15
15895	Envitec Oxygen Sensors Product Changes revised serial number fo...	02/11/15
15870	Envitec Oxygen Sensors Competitors Information and Patients Air ...	29/10/15
15743	Envitec Oxygen Sensors viamed Labels	29/09/15
15591	Envitec CE	07/09/15
15589	Envitec Oxygen Sensors Expected Use By Date rational for not usi...	03/09/15
15588	Envitec Oxygen Sensors Expected Life of Products Use By Dates Ra...	03/09/15
15496	Envitec Oxygen Sensors OES (OEM) Specifications (22)	14/08/15
15494	Envitec Oxygen Sensors OES (OEM) Specifications (20)	14/08/15
15493	Envitec Oxygen Sensors OES (OEM) Specifications (19)	14/08/15
15492	Envitec Oxygen Sensors OES (OEM) Specifications (18)	14/08/15
15491	Envitec Oxygen Sensors OES (OEM) Specifications (17)	14/08/15
15490	Envitec Oxygen Sensors OES (OEM) Specifications (16)	14/08/15
15489	Envitec Oxygen Sensors OES (OEM) Specifications (15)	14/08/15
15488	Envitec Oxygen Sensors OES (OEM) Specifications (14)	14/08/15
15487	Envitec Oxygen Sensors OES (OEM) Specifications (13)	14/08/15
15486	Envitec Oxygen Sensors OES (OEM) Specifications (12)	14/08/15
15485	Envitec Oxygen Sensors OES (OEM) Specifications (11)	14/08/15
15484	Envitec Oxygen Sensors OES (OEM) Specifications (10)	14/08/15
15483	Envitec Oxygen Sensors OES (OEM) Specifications (9)	14/08/15
15482	Envitec Oxygen Sensors OES (OEM) Specifications (8)	14/08/15
15481	Envitec Oxygen Sensors OES (OEM) Specifications (7)	14/08/15
15480	Envitec Oxygen Sensors OES (OEM) Specifications (6)	14/08/15
15479	Envitec Oxygen Sensors OES (OEM) Specifications (5)	14/08/15
15478	Envitec Oxygen Sensors OES (OEM) Specifications (4)	14/08/15
15477	Envitec Oxygen Sensors OES (OEM) Specifications (3)	14/08/15
15476	Envitec Oxygen Sensors OES (OEM) Specifications (2)	14/08/15
15475	Envitec Oxygen Sensors OES (OEM) Specifications (1)	14/08/15
15474	Envitec Oxygen Sensors Expected Life of Products	14/08/15
15467	Vandagraph VST Sensors Instructions for Use User Manual	14/08/15
15456	Envitec Oxygen Sensors OES (OEM) Lables for OBLs	13/08/15
15455	Envitec Oxygen Sensors Description of Device	12/08/15
15418	PPE Equipment	11/08/15
15143	Envitec Oxygen Sensors Specifications Envitec OOM-106 datasheet ...	09/07/15
14996	Viamed ISO CE Certificate Private Labelling Envitec 97289 obl CO...	18/05/15
14792	EnviteC-Wismar GmbH Declaration Conformity Oxygen Sensors	19/02/15
14791	EnviteC-Wismar GmbH ISO 13485	19/02/15

Document ID	Description	Date Added/Updated
14790	EnviteC-Wismar GmbH ISO 9001	19/02/15
14549	Envitec Oxygen Sensors Post Market Surveillance	12/11/14

Comments on Document Changes:

specification updates to sensors due to the inner component change

Comments on Risks with Document Changes:

no risk identified with product changes

Internal Issues Review

Number of Issues reviewed: 481

Issue ID	Subject
57952	0110021 R-22MEDV sensors and matched pairs for Oxylink
57951	0110021 R-22MEDV sensors and matched pairs for Oxylink
57950	0110021 R-22MEDV sensors and matched pairs for Oxylink
57949	0110021 R-22MEDV sensors and matched pairs for Oxylink
57948	0110021 R-22MEDV sensors and matched pairs for Oxylink
57947	0110021 R-22MEDV sensors and matched pairs for Oxylink
57946	0110021 R-22MEDV sensors and matched pairs for Oxylink
55656	0110022 matched pair order from Northampton General
55655	0110022 matched pair order from Northampton General
55654	0110022 matched pair order from Northampton General
55653	0110022 matched pair order from Northampton General
62516	0110023 for evaluation trial - University of Hartlepool
66380	0110040 design change approval for technical file.
63193	0110045 packaging
51668	0110048 marketing schedule R-48V
52959	0110049 R-49V Oxygen Sensor
59603	0110071 Barcode
58773	0110071 R-22MEDV matched pairs tolerance values
68392	0120092 to order
54135	0120096, 0120097
53316	18mm OD flow sensor availability
56200	18mm OD flow sensor divertor for R-26MED as used on Stephan F120
69604	25 x 0110048
59179	Backorder 00000065 0110023 ORD74268
62116	Backorder 00000065 0110023 ORD75757
64695	Backorder 00000096 0110048 ORD77074
55825	Backorder 00000126 0110023 ORD72196
61569	Backorder 00000127 0110071 ORD75477
59196	Backorder 00000128 0110040 ORD74259
66404	Backorder 00000128 0110040 ORD78079
65569	Backorder 00000129 0110023 ORD77597
60117	Backorder 00000233 0110023 ORD74863
61055	Backorder 00000233 0110023 ORD75235
61830	Backorder 00000233 0110023 ORD75590
65327	Backorder 00000233 0110023 ORD77458
69084	Backorder 00000233 0110071 ORD79437
56190	Backorder 00000239 0110023 ORD72386
58475	Backorder 00000333 0110023 ORD73842
63326	Backorder 00000333 0110023 ORD76333
56704	Backorder 00000450 0110023 ORD72680
61987	Backorder 00000501 0110071 ORD75684
54657	Backorder 00000516 0110023 ORD71479

Issue ID	Subject
55838	Backorder 00000550 0110023 ORD72211
68267	Backorder 00000570 0110023 ORD79057
67467	Backorder 00000580 0110049 ORD78675
63979	Backorder 00000600 0110071 ORD76761
62288	Backorder 00000620 0110071 ORD75866
65740	Backorder 00000620 0110071 ORD77703
66661	Backorder 00000620 0110071 ORD78217
56676	Backorder 00000680 0110023 ORD72646
58069	Backorder 00000680 0110023 ORD73600
67113	Backorder 00000680 0110023 ORD78538
63537	Backorder 00000680 0110042 ORD76445
55292	Backorder 00000690 0110023 ORD71920
55257	Backorder 00000700 0110023 ORD71872
58707	Backorder 00000700 0110023 ORD73991
66936	Backorder 00000713 0110040 ORD78447
67465	Backorder 00000740 0110040 ORD78685
62113	Backorder 00000742 0110023 ORD75753
58595	Backorder 00000742 0110040 ORD73927
63264	Backorder 00000742 0110040 ORD76284
64295	Backorder 00000742 0110040 ORD76907
65458	Backorder 00000742 0110040 ORD77535
56189	Backorder 00000790 0110021 ORD72429
60690	Backorder 00000790 0110071 ORD75120
57384	Backorder 00000838 0110047 ORD73187
55743	Backorder 00000860 0110023 ORD72095
57344	Backorder 00000860 0110043 ORD73162
58857	Backorder 00000860 0110043 ORD74095
69077	Backorder 00000980 0110023 ORD79425
58226	Backorder 00001040 0110043 ORD73673
59756	Backorder 00001040 0110043 ORD74634
60305	Backorder 00001040 0110043 ORD74930
66108	Backorder 00001040 0110043 ORD77952
61709	Backorder 00001043 0110023 ORD75546
62630	Backorder 00001045 0110040 ORD76018
63056	Backorder 00001060 0110071 ORD76180
56195	Backorder 00001170 0110023 ORD72437
58891	Backorder 00001170 0110023 ORD74114
60335	Backorder 00001170 0110023 ORD74970
62693	Backorder 00001170 0110023 ORD76038
68263	Backorder 00001170 0110023 ORD79063
65150	Backorder 00001184 0110040 ORD77338
56601	Backorder 00001241 0110043 ORD72606
57175	Backorder 00001270 0110023 ORD73040
58348	Backorder 00001270 0110023 ORD73769
61326	Backorder 00001270 0110023 ORD75401

Issue ID	Subject
63431	Backorder 00001270 0110023 ORD76387
65724	Backorder 00001270 0110023 ORD77605
56480	Backorder 00001320 0110021 ORD72534
56443	Backorder 00001320 0110023 ORD72506
65836	Backorder 00001320 0110023 ORD77789
57929	Backorder 00001320 0110071 ORD73490
61184	Backorder 00001320 0110071 ORD75322
68065	Backorder 00001320 0110071 ORD78965
60163	Backorder 00001390 0110071 ORD74876
56257	Backorder 00001410 0110071 ORD72461
70206	Backorder 00001415 0110071 ORD79841
56782	Backorder 00001420 0110023 ORD72756
58352	Backorder 00001480 0110021 ORD73772
54329	Backorder 00001480 0110023 ORD71234
55293	Backorder 00001500 0110023 ORD71923
62876	Backorder 00001500 0110023 ORD76102
69078	Backorder 00001500 0110023 ORD79434
59740	Backorder 00001520 0110023 ORD74614
64304	Backorder 00001520 0110023 ORD76910
66555	Backorder 00001520 0110023 ORD78166
54956	Backorder 00001520 0110071 ORD71694
63859	Backorder 00001520 0110071 ORD76658
66696	Backorder 00001520 0110071 ORD78233
59744	Backorder 00001521 0110023 ORD74608
70031	Backorder 00001521 0110023 ORD79789
61302	Backorder 00001521 0110071 ORD75379
65284	Backorder 00001601 0110071 ORD77417
55137	Backorder 00001820 0110023 ORD71793
59143	Backorder 00001820 0110023 ORD74238
62938	Backorder 00001850 0110023 ORD76131
65884	Backorder 00001850 0110023 ORD77836
54891	Backorder 00001870 0110023 ORD71626
58172	Backorder 00001870 0120090 ORD73640
57971	Backorder 00001880 0110023 ORD73527
61940	Backorder 00001902 0110023 ORD75656
57040	Backorder 00001902 0110071 ORD72942
61494	Backorder 00001902 0110071 ORD75445
62364	Backorder 00001902 0110071 ORD75896
63619	Backorder 00001902 0110071 ORD76505
65242	Backorder 00001902 0110071 ORD77402
61570	Backorder 00002020 0110040 ORD75480
62939	Backorder 00002020 0110040 ORD76132
68487	Backorder 00002020 0110040 ORD79153
61726	Backorder 00002020 0110071 ORD75557
63759	Backorder 00002040 0110023 ORD76563

Issue ID	Subject
65121	Backorder 00002040 0110023 ORD77330
69696	Backorder 00002040 0110023 ORD79680
55841	Backorder 00002040 0110071 ORD72214
56865	Backorder 00002040 0110071 ORD72798
60531	Backorder 00002040 0110071 ORD75024
60579	Backorder 00002040 0110071 ORD75050
64215	Backorder 00002040 0110071 ORD76871
63948	Backorder 00002080 0110071 ORD76726
64017	Backorder 00002080 0110071 ORD76770
64692	Backorder 00002080 0110071 ORD77078
66689	Backorder 00002081 0110023 ORD78234
65287	Backorder 00002081 0110071 ORD77419
61101	Backorder 00002100 0110021 ORD75261
63349	Backorder 00002130 0110023 ORD76337
64005	Backorder 00002130 0110048 ORD76756
57041	Backorder 00002152 0110071 ORD72927
58173	Backorder 00002152 0110071 ORD73638
63184	Backorder 00002152 0110071 ORD76256
65787	Backorder 00002152 0110071 ORD77759
65333	Backorder 00002191 0110023 ORD77469
63861	Backorder 00002250 0110040 ORD76662
66142	Backorder 00002285 0110023 ORD77965
57258	Backorder 00002286 0110023 ORD73090
58653	Backorder 00002286 0110023 ORD73980
69525	Backorder 00002286 0110023 ORD79622
69519	Backorder 00002320 0110021 ORD79617
57500	Backorder 00002323 0110023 ORD73275
55872	Backorder 00002323 0110071 ORD72238
59759	Backorder 00002323 0110071 ORD74622
66311	Backorder 00002323 0110071 ORD78050
54735	Backorder 00002360 0110071 ORD71550
58342	Backorder 00002360 0110071 ORD73775
60201	Backorder 00002360 0110071 ORD74901
59243	Backorder 00002400 0110043 ORD74295
67893	Backorder 00002420 0110041 ORD78893
56262	Backorder 00002420 0110071 ORD72454
60924	Backorder 00002420 0110071 ORD75164
65571	Backorder 00002420 0110071 ORD77600
68131	Backorder 00002420 0110071 ORD78893
61102	Backorder 00002434 0110023 ORD75262
61982	Backorder 00002434 0110023 ORD75672
57470	Backorder 00002435 0110023 ORD73269
65238	Backorder 00002470 0110071 ORD77393
63098	Backorder 00002471 0110071 ORD76190
55475	Backorder 00002500 0110023 ORD72006

Issue ID	Subject
57965	Backorder 00002500 0110023 ORD73518
54833	Backorder 00002590 0110023 ORD71606
57318	Backorder 00002590 0110040 ORD73136
59683	Backorder 00002590 0110040 ORD74584
64253	Backorder 00002590 0110040 ORD76883
67850	Backorder 00002590 0110040 ORD78876
54656	Backorder 00002600 0110043 ORD71492
58887	Backorder 00002600 0110043 ORD74106
60609	Backorder 00002600 0110043 ORD75068
61983	Backorder 00002600 0110043 ORD75675
62865	Backorder 00002600 0110043 ORD76100
65834	Backorder 00002609 0110040 ORD77775
69522	Backorder 00002609 0110040 ORD79613
61705	Backorder 00002609 0110043 ORD75543
56703	Backorder 00002641 0110023 ORD72672
59954	Backorder 00002690 0110023 ORD74757
65190	Backorder 00002690 0110023 ORD77376
66501	Backorder 00002690 0110023 ORD78139
69521	Backorder 00002690 0110023 ORD79611
57526	Backorder 00002690 0110040 ORD73288
57225	Backorder 00002690 0110043 ORD73062
65459	Backorder 00002690 0110043 ORD77537
61127	Backorder 00002710 0110023 ORD75289
59248	Backorder 00002790 0110023 ORD74305
65779	Backorder 00002790 0110023 ORD77741
61104	Backorder 00002950 0110042 ORD75272
66107	Backorder 00003070 0110071 ORD77949
59623	Backorder 00003095 0110041 ORD74536
59606	Backorder 00003450 0110023 ORD74493
59440	Backorder 00003450 0110048 ORD74445
69909	Backorder 00003450 0110071 ORD79762
63519	Backorder 00003460 0110045 ORD76432
60571	Backorder 00003463 0110040 ORD75038
59281	Backorder 00003463 0110071 ORD74334
63531	Backorder 00003463 0110071 ORD76448
63550	Backorder 00003490 0110023 ORD76454
61488	Backorder 00003500 0110045 ORD75435
56754	Backorder 00003500 0110071 ORD72738
60172	Backorder 00003500 0110071 ORD74885
62226	Backorder 00003500 0110071 ORD75818
69478	Backorder 00003500 0110071 ORD79589
56705	Backorder 00003560 0110023 ORD72689
57042	Backorder 00003560 0110023 ORD72944
59026	Backorder 00003560 0110023 ORD74193
58532	Backorder 00003580 0110071 ORD73910

Issue ID	Subject
66632	Backorder 00003580 0110071 ORD78190
56624	Backorder 00003601 0110023 ORD72627
57803	Backorder 00003640 0110023 ORD73418
58391	Backorder 00003640 0110023 ORD73798
59282	Backorder 00003640 0110023 ORD74343
62099	Backorder 00003640 0110023 ORD75737
63108	Backorder 00003640 0110023 ORD76207
67168	Backorder 00003640 0110023 ORD78551
62762	Backorder 00003640 0110047 ORD76070
60345	Backorder 00003640 0110071 ORD74981
60466	Backorder 00003640 0110071 ORD75003
62190	Backorder 00003640 0110071 ORD75793
67378	Backorder 00003640 0110071 ORD78639
61130	Backorder 00003665 0110040 ORD75287
65302	Backorder 00003665 0110040 ORD77436
68268	Backorder 00003665 0110040 ORD79049
57383	Backorder 00003665 0110043 ORD73199
67308	Backorder 00003668 0110040 ORD78614
55382	Backorder 00003780 0110023 ORD71976
64104	Backorder 00003780 0110023 ORD76815
65328	Backorder 00003780 0110023 ORD77459
54848	Backorder 00003785 0110023 ORD71588
56449	Backorder 00003785 0110023 ORD72516
57632	Backorder 00003785 0110023 ORD73345
57783	Backorder 00003785 0110023 ORD73397
63688	Backorder 00003785 0110023 ORD76549
66279	Backorder 00003785 0110023 ORD78017
67247	Backorder 00003785 0110047 ORD78596
55647	Backorder 00003800 0110023 ORD72046
63662	Backorder 00003800 0110023 ORD76531
65560	Backorder 00003800 0110023 ORD77584
68428	Backorder 00003800 0110023 ORD79127
64022	Backorder 00003930 0110071 ORD76772
60880	Backorder 00003940 0110048 ORD75165
64610	Backorder 00003970 0110023 ORD77033
58704	Backorder 00003970 0110071 ORD73997
58851	Backorder 00003970 0110071 ORD74080
64300	Backorder 00003970 0110071 ORD76914
60203	Backorder 00004040 0110023 ORD74895
65332	Backorder 00004040 0110040 ORD77466
69856	Backorder 00004040 0110048 ORD79740
57907	Backorder 00004080 0110023 ORD73466
62287	Backorder 00004080 0110023 ORD75868
65195	Backorder 00004080 0110023 ORD77369
67731	Backorder 00004080 0110023 ORD78817

Issue ID	Subject
69400	Backorder 00004080 0110023 ORD79545
56052	Backorder 00004295 0110023 ORD72373
58744	Backorder 00004295 0110071 ORD74035
65189	Backorder 00004300 0110071 ORD77368
58222	Backorder 00004400 0110023 ORD73658
61892	Backorder 00004400 0110023 ORD75595
67983	Backorder 00004400 0110023 ORD78915
58474	Backorder 00004400 0110071 ORD73839
58219	Backorder 00004435 0110048 ORD73653
59620	Backorder 00004507 0110023 ORD74540
66631	Backorder 00004507 0110071 ORD78189
62342	Backorder 00004510 0110040 ORD75890
60470	Backorder 00004561 0110023 ORD75006
67897	Backorder 00004561 0110023 ORD78888
57172	Backorder 00004570 0110023 ORD73034
55291	Backorder 00004710 0110023 ORD71922
56188	Backorder 00004735 0110071 ORD72425
61482	Backorder 00004735 0110071 ORD75440
68380	Backorder 00004735 0110071 ORD79106
54914	Backorder 00004891 0110071 ORD71652
55255	Backorder 00004891 0110071 ORD71760
58716	Backorder 00005030 0110071 ORD74006
65566	Backorder 00005040 0110023 ORD77593
57347	Backorder 00005072 0110023 ORD73161
57321	Backorder 00005101 0110023 ORD73135
56944	Backorder 00005110 0110043 ORD72869
65976	Backorder 00005110 0110043 ORD77886
67640	Backorder 00005129 0110071 ORD78795
63459	Backorder 00005130 0110071 ORD76396
56902	Backorder 00005135 0110071 ORD72843
58649	Backorder 00005135 0110071 ORD73971
55839	Backorder 00005140 0110023 ORD72212
57553	Backorder 00005140 0110023 ORD73304
57904	Backorder 00005140 0110023 ORD73467
58600	Backorder 00005140 0110023 ORD73932
59316	Backorder 00005140 0110023 ORD74360
63710	Backorder 00005140 0110023 ORD76555
66403	Backorder 00005140 0110023 ORD78078
67543	Backorder 00005140 0110023 ORD78742
60610	Backorder 00005240 0110023 ORD75069
65293	Backorder 00005240 0110023 ORD77432
60608	Backorder 00005240 0110071 ORD75067
58991	Backorder 00005250 0110040 ORD74176
54829	Backorder 00005430 0110071 ORD71602
60045	Backorder 00005430 0110071 ORD74807

Issue ID	Subject
66397	Backorder 00005445 0120099 ORD78058
66645	Backorder 00005445 0120099 ORD78212
60338	Backorder 00005500 0110023 ORD74978
60691	Backorder 00005500 0110023 ORD75122
65015	Backorder 00005520 0110040 ORD77279
69644	Backorder 00005520 0110040 ORD79664
59870	Backorder 00005520 0110071 ORD74695
59755	Backorder 00006003 0110023 ORD74379
54602	Backorder 00006027 0110023 ORD71448
55688	Backorder 00006027 0110023 ORD72033
56438	Backorder 00006027 0110023 ORD72498
57761	Backorder 00006027 0110023 ORD73382
61683	Backorder 00006027 0110023 ORD75228
66669	Backorder 00006027 0110023 ORD78219
69122	Backorder 00006027 0110023 ORD79445
54093	Backorder 00006065 0110023 ORD71068
62539	Backorder 00006078 0110045 ORD75910
57655	Backorder 00006108 0110023 ORD73351
60112	Backorder 00006108 0110023 ORD74792
67442	Backorder 00006156 0110041 ORD78567
65239	Backorder 00006158 0110023 ORD77398
62239	Backorder 00006175 0110045 ORD75832
66768	Backorder 00006176 0110023 ORD78300
66205	Backorder 00006176 0110041 ORD78001
64004	Backorder 00006176 0110049 ORD76763
66228	Backorder 00006176 0110049 ORD78001
69126	Backorder 00006224 0110021 ORD79458
58011	Backorder 00006241 0110023 ORD73526
67767	Backorder 00006241 0110023 ORD78824
63945	Backorder 00006305 0110044 ORD76721
69392	Backorder 00006337 0110021 ORD79537
60604	Backorder 00006673 0110023 ORD75054
54536	Backorder 00006673 0110043 ORD71389
54438	Backorder 00006676 0110023 ORD71312
56253	Backorder 00006676 0110023 ORD72448
60646	Backorder 00006676 0110023 ORD75089
61182	Backorder 00006676 0110023 ORD75318
56930	Backorder 00006676 0110047 ORD72857
60469	Backorder 00006676 0110047 ORD75004
62624	Backorder 00006695 0110040 ORD76013
59343	Backorder 00007020 0110040 ORD73884
66803	Backorder 00007033 0110049 ORD78206
66245	Backorder 00007125 0110023 ORD78028
58317	Backorder 00007138 0110021 ORD73747
58796	Backorder 00007138 0110023 ORD74067

Issue ID	Subject
64500	Backorder 00007157 0110021 ORD76988
59144	Backorder 00007356 0110023 ORD74242
55051	Backorder 00007468 0110021 ORD71608
63179	Backorder 00007518 0110021 ORD76248
63653	Backorder 00007518 0110023 ORD76529
65322	Backorder 00007518 0110023 ORD77450
69104	Backorder 00007518 0110023 ORD79446
55289	Backorder 00007527 0110023 ORD71929
65975	Backorder 00007531 0110023 ORD77885
57495	Backorder 00007603 0110042 ORD73272
58971	Backorder 00007679 0110040 ORD74153
62269	Backorder 00007883 0110021 ORD75841
65281	Backorder 00007883 0110021 ORD77418
70146	Backorder 00007883 0110044 ORD79815
68851	Backorder 00007883 0110047 ORD79273
57942	Backorder 00007883 0110071 ORD73520
54410	Backorder 00009190 0110041 ORD71298
63394	Backorder 00009190 0110041 ORD76353
64620	Backorder 00009190 0110041 ORD77036
65489	Backorder 00009190 0110041 ORD77550
69465	Backorder 00009190 0110041 ORD79581
59619	Backorder 00012132 0110043 ORD74538
57177	Backorder 00012178 0110040 ORD73042
59252	Backorder 00012178 0110040 ORD74296
51994	Backorder 00012240 0110021 ORD69760
55995	Backorder 00012240 0110021 ORD72326
57575	Backorder 00012240 0110021 ORD73326
60686	Backorder 00012240 0110021 ORD75110
61364	Backorder 00012240 0110021 ORD75419
62563	Backorder 00012240 0110021 ORD75987
63686	Backorder 00012240 0110021 ORD76545
66886	Backorder 00012240 0110021 ORD78423
66727	Backorder 00012240 0110043 ORD78264
57223	Backorder 00012240 0110047 ORD73054
59609	Backorder 00012240 0110047 ORD74532
61460	Backorder 00012240 0110047 ORD75420
61773	Backorder 00012240 0110047 ORD75589
67464	Backorder 00012240 0110047 ORD78684
63889	Backorder 00012304 0110040 ORD76686
65725	Backorder 00012605 0111275 ORD77670
67314	Backorder 00012672 0110040 ORD78618
55908	Backorder 00012698 0110023 ORD72215
57343	Backorder 00012714 0110040 ORD73163
68729	Backorder 00012750 0110117 ORD79200
68853	Backorder 00012750 0120092 ORD79200

Issue ID	Subject
60648	Backorder 00012931 0111275 ORD75097
60649	Backorder 00012931 0111275 ORD75098
62006	Declaration of Compatibility 0110049 - Siemens 64 19 332 E380E
65468	Document Update Request (14367)
58636	Document/Picture (DOCID14212) Update Request
55280	Document/Picture (DOCID14458) Update Request
58637	Document/Picture (DOCID14980) Update Request
60671	Document/Picture (DOCID15162) Update Request
65847	Document/Picture (DOCID16110) Update Request
58366	Document/Picture (DOCID7266) Update Request
62004	Envitec & Viamed oxygen sensors - use by date
66163	Envitec investigation results required
60437	GCC Registration - Saudi - Jamjoom
60436	GCC Registration - Saudi - Jamjoom
44817	Group Peto Group - Export
55276	Incomplete SRS to tidy
69127	Instructions for Use - Viamed Medical Oxygen Sensors 2016-03-29
62122	Leaflet OxiQuant S Oxygen Analyser PDFs generated for L
41685	Lost customers for a stock group
61014	Mailshot Lost Customers
54003	Marketing Schedule 0110048 R-48V Confirm/Calculate pricing
52211	Marketing Schedule 0110048 R-48V Datasheet to Z for L
52138	Marketing Schedule 0110048 R-48V Declaration of Conformity to Z for L
52124	Marketing Schedule 0110048 R-48V Verify Covering CE
52123	Marketing Schedule 0110048 R-48V Verify/Add to Cross Reference Database
56161	Marketing Schedule 0110049 R-49V Oxygen Sensor Declaration of Compatibility to Z for L
53279	Marketing Schedule 0110049 R-49V Oxygen Sensor Declaration of Conformity to Z for L
54575	Oxygen sensors added to the range
54574	Oxygen sensors added to the range
54573	Oxygen sensors added to the range
54572	Oxygen sensors added to the range
54571	Oxygen sensors added to the range
54570	Oxygen sensors added to the range
54569	Oxygen sensors added to the range
54568	Oxygen sensors added to the range
54567	Oxygen sensors added to the range
54566	Oxygen sensors added to the range
54565	Oxygen sensors added to the range
55282	Oxygen sensors added to the range: OEM issues
53252	Oxygen Sensors Specification Information required
54960	Oxylink
54959	Oxylink
58147	Parts to order from Envitec
59696	Please order another 5 x 0111275 from Envitec
61532	POR10292 0110021 Have Been Delivered or Cancelled in Opera

Issue ID	Subject
61531	POR10292 0110021 Have Been Delivered or Cancelled in Opera
63204	POR10344 0110045 Have Been Delivered or Cancelled in Opera
69550	POR10684 0110023 25/05/2016
69615	POR10687 0110021 //
69699	POR10687 0110021 10/05/2016
70050	POR10688 0110048 //
69614	POR10688 0110048 //
70051	POR10698 0110023 //
69915	POR10698 0110023 //
70052	POR10698 0110023 09/06/2016
59975	Private labelling artwork - Viamed Oxygen Sensors
61019	R-22MED and R-22MEDV Lost Customers
55275	R-22MEDV matched pair problems
68453	R-23V & R-30V Pricing in Poland
59748	R-23V - 0110023 - New sensors Tarnished
59746	R-23V - 0110023 - New sensors Tarnished
60872	R-30
58134	R-48V compatibility
64793	R-75V SMART oxygen sensors
59855	R22-MEDV matched pairs - tighter matching spec
62538	Request Scanning Item to Sale or return
62537	Request Scanning Item to Sale or return
67114	Reserve Stock for Sunshine Medical a/c 00006156 - PRO03594
57986	Saudi delegation visit to Germany
54761	Stock booked in in error
68287	Thermoseal NM Argon - product build inconsistencies
70248	Urgent oxygen sensor order to go out today
70247	Urgent oxygen sensor order to go out today
70246	Urgent oxygen sensor order to go out today
70245	Urgent oxygen sensor order to go out today
70244	Urgent oxygen sensor order to go out today
57916	Web Site Question ID 441
59891	Web Site Question ID 503
67012	Website updates

Comments on Issues:

Mainly sales issues, and the product innner casing changes,
no problems identified in the issues system

Comments on Risks with Issues:

no risks identified in the issues system

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Component of Main device, no specific clinical data found.

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

no FDA recalls found relating to the device/component