



VIA MED

Envitec Oxygen Sensors

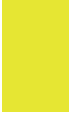
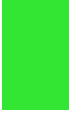
A medical device for measuring the proportion of oxygen in respiration gases.

Class IIa
Via Rule 10
Assesment Route Annex II

Carried out by Derek Lamb
16 / 05 / 17



VIA MED

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

Stock References Review

Stock Reference	Description
0110018	Oxygen sensor R-17V
0110019	Oxygen sensor R-17Vi
0110020	Oxygen sensor R-22Vi
0110021	Oxygen sensor R-22MEDV
0110023	Oxygen sensor R-23V
0110025	Oxygen sensor R-23Vi
0110039	Oxygen sensor R-22VA.
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
0110047	Oxygen sensor R-47V
0110048	Oxygen sensor R-48V
0110049	Oxygen sensor R-49V
0110071	Oxygen sensor R-22MEDV. Pack of 2
0110072	Oxygen sensor R-22Vi. Pack of 2
0110073	Oxygen sensor R-22VA. Pack of 2
0110075	Oxygen sensor R-75V
0110560	Oxygen sensor OOM111
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.
R212P75-001	Front Cover for OM-25ME
R212P91	Battery cover for OM25-AE
R212P95-001	Dove tail bracket for OM25-ME
R213P42	Rear cover for OM25-AE includes:

Comments on Stock references review:

Stock references upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0110018	Oxygen sensor R-17V	00007282	01-00-0016	EnviteC-Wismar GmbH	A
0110019	Oxygen sensor R-17Vi	00007282	01-00-0020	EnviteC-Wismar GmbH	A
0110020	Oxygen sensor R-22Vi	00007282	01-00-0019	EnviteC-Wismar GmbH	A
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
0110025	Oxygen sensor R-23Vi	00007282	01-00-0049	EnviteC-Wismar GmbH	A
0110039	Oxygen sensor R-22VA.	00007282		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
0110075	Oxygen sensor R-75V	00007282		EnviteC-Wismar GmbH	A
0110560	Oxygen sensor OOM111	00007282	01-00-0114	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
0120095	Oxygen sensor flow diver	00011712	R110P10-001	Maxtec Inc.	B
0120096	Oxygen sensor flow diver	00011712	RP56P03-002	Maxtec Inc.	B
0120097	Oxygen sensor flow diver	00011712	RP33P42-002	Maxtec Inc.	B
R212P75-001	Front Cover for OM-25ME	00011712	R212P75-001	Maxtec Inc.	B
R212P91	Battery cover for OM25-A	00011712	R212P91	Maxtec Inc.	B
R212P95-001	Dove tail bracket for OM	00011712	R212P95-001	Maxtec Inc.	B
R213P42	Rear cover for OM25-AE i	00011712	R213P42	Maxtec Inc.	B

Comments on Suppliers:

Maxtec showing as supplier due to them supplying the parts in the past.

Same with Teledyne Sensors which have been replaced with envitec versions

Envitec ISO certificates upto date.

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0110018	Oxygen sensor R-17V							
0110019	Oxygen sensor R-17Vi							50
0110020	Oxygen sensor R-22Vi							
0110021	Oxygen sensor R-22MEDV	68	27	49	1339	1740	1395	573
0110023	Oxygen sensor R-23V	2255	1226	1432	1930	1891	1711	474
0110025	Oxygen sensor R-23Vi							
0110039	Oxygen sensor R-22VA.							
0110040	Oxygen sensor R-30V	445	267	340	495	554	536	209
0110041	Oxygen sensor R-41V	16	19	70	116	101	114	33
0110042	Oxygen sensor R-42V	45	35	87	89	33	32	24
0110043	Oxygen sensor R-43V. Pa	471	216	234	310	270	298	111
0110044	Oxygen sensor R-44V	20	4	6	12	8	4	3
0110045	Oxygen sensor R-45V	13		2	78	80	64	51
0110047	Oxygen sensor R-47V	73	64	161	304	363	251	9
0110048	Oxygen sensor R-48V					40	122	65
0110049	Oxygen sensor R-49V				2	101	147	68
0110071	Oxygen sensor R-22MEDV. Pack of 2	441	300	494	490	642	607	197
0110072	Oxygen sensor R-22Vi. Pack of 2							10
0110073	Oxygen sensor R-22VA. Pack of 2							2
0110075	Oxygen sensor R-75V						22	
0110560	Oxygen sensor OOM111						15	8
0111275	Oxygen analyser OxiQuant					5	10	7
0120090	Oxygen sensor O ring.	60	20	20	11	10		
0120091	Oxygen sensor O ring for			20				
0120092	Oxygen sensor flow diver						30	3
0120095	Oxygen sensor flow diver							6
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.	161	86	110	70	30	61	7
R212P75-001	Front Cover for OM-25ME						3	2
R212P91	Battery cover for OM25-A	5	5	11		7	15	2
R212P95-001	Dove tail bracket for OM		20	1		5		
R213P42	Rear cover for OM25-AE i						2	2

Comments on Sales Information:

Sensor sales still selling well.

new ranges coming on board

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
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]	[X]	
CH Chile							
CY Cyprus		[X]					
CZ Czech Republic			[X]	[X]	[X]	[X]	[X]
DE Denmark	[X]	[X]				[X]	
EG Egypt	[X]						
ES Estonia				[X]			
F France		[X]	[X]	[X]	[X]	[X]	[X]
FI Finland						[X]	[X]
G Germany	[X]		[X]		[X]	[X]	[X]
GEO Georgia	[X]						
GR Greece	[X]	[X]	[X]	[X]	[X]	[X]	[X]
HU Hungary			[X]	[X]		[X]	
I Iran					[X]		
IN India	[X]		[X]	[X]	[X]	[X]	
IRE Ireland	[X]	[X]	[X]	[X]	[X]	[X]	
IS Israel	[X]	[X]	[X]	[X]	[X]	[X]	[X]
IT Italy	[X]	[X]				[X]	
J Japan							
JO Jordan		[X]			[X]	[X]	[X]
KE Kenya			[X]	[X]	[X]		
KU Kuwait							
LA Latvia		[X]	[X]	[X]	[X]		
LEB Lebanon	[X]	[X]	[X]	[X]	[X]	[X]	[X]
LI Lithuania	[X]	[X]	[X]	[X]	[X]	[X]	[X]
LIB Libya		[X]		[X]	[X]	[X]	
MA Malaysia	[X]	[X]	[X]	[X]	[X]	[X]	[X]
MAC Macedonia			[X]				
MEX Mexico						[X]	
MO Morrocco	[X]	[X]	[X]	[X]	[X]	[X]	
NE Netherlands			[X]				
NEP Nepal		[X]					
NG Nigera		[X]					
NO Norway							

Country	2011	2012	2013	2014	2015	2016	2017
OM Oman	[X]				[X]		
P Poland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
PA Pakistan					[X]	[X]	[X]
PAL Palestine				[X]			
PE Peru						[X]	
PH Philippines	[X]		[X]	[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]	[X]
SAU Saudi Arabia	[X]	[X]	[X]	[X]		[X]	
SER Serbia	[X]	[X]	[X]	[X]	[X]	[X]	
SI Singapore		[X]					
SL Slovenia		[X]	[X]	[X]	[X]	[X]	
SP Spain			[X]	[X]	[X]	[X]	[X]
SRI Sri Lanka	[X]				[X]	[X]	
SU Sudan							[X]
SW Sweden							
SWI Switzerland	[X]						
SY Syria							
SZ Swaziland						[X]	
T Turkey	[X]						
TH Thailand							
UAE U A E	[X]		[X]	[X]	[X]	[X]	[X]
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
UKR Ukraine						[X]	[X]
USA USA							
VE Venezuela			[X]				
VI Vietnam		[X]	[X]				

Comments on Sales to Countries:

units selling world wide

Comments on Risks with Sales to Countries:

no risks with selling to different countries

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0110021	Declined Repair					1		
0110021	Low Output						1	
0110021	New		2			8		
0110021	No Fault Found		1			2		
0110021	No Fault Return to Stock						9	
0110021	No output					2		
0110021	Unchecked - Returned to Stock	1					4	
0110021	Unstable		1			1		
0110023	Needs Evaluating	1				1	15	22
0110023	Bubble in electrolyte		2	3	10	7	4	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	New		1			1		
0110023	No Fault Found	1						
0110023	No Fault Return to Stock							
0110023	No output				1			
0110023	No output - During Use							
0110023	Non Linear - During Use							
0110023	Offset failure							
0110023	Rising output - During Use							
0110023	Tarnished input ring					9		
0110023	Unchecked - Returned to Stock		2		3		12	
0110023	Unstable		1		2		2	
0110023	Will not Calibrate - During Use							
0110040	Calibration failed						2	
0110040	Fluctuating o/p - During Use		1					
0110040	High output - will not calibrate			1				
0110040	Low Output			2				
0110040	New				1			
0110040	No Fault Found	2	1	1				
0110040	Slow response							1
0110040	Unable to repair						1	
0110040	Will not Calibrate - During Use			1				
0110041	Needs Evaluating						3	
0110041	Low Output			1				

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0110041	New			1				
0110041	Unstable			1				
0110042	Needs Evaluating		4					
0110042	Cable fault		3					
0110042	New					1		
0110042	Unchecked - Returned to Stock	1						
0110043	Bubble in electrolyte		2	7	2			
0110043	Calibration failed						4	
0110043	End of life		3					
0110043	Low Output	1			6			
0110043	Mismatched							1
0110043	No Fault Found				1			
0110043	Not a matched pair						1	
0110043	Slow response							1
0110043	Unchecked - Returned to Stock					2		
0110043	Unstable			1				
0110043	Will not Calibrate - During Use						3	
0110044	Needs Evaluating		1					
0110044	Unchecked - Returned to Stock			3				
0110045	Calibration failed		1			1		
0110045	Low Output				1			
0110045	New	1						
0110045	No output				2			
0110047	Calibration failed		3			1	1	
0110047	Fluctuating o/p - During Use		1			1		
0110047	Low Output						1	1
0110047	No Fault Found					1		
0110047	No Fault Return to Stock						6	
0110071	Needs Evaluating						15	
0110071	Both cells faulty			2	1			
0110071	Calibration failed		4	5	1	6	20	
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	1	2
0110071	Low output , between 7 - 9 mV							1
0110071	Mismatched							2
0110071	New			2		2		
0110071	No Fault Found		5	3	1	3		
0110071	No Fault Return to Stock							2
0110071	No output				1			
0110071	Not a matched pair		1	2	1	8	18	10
0110071	Offset failure					1		
0110071	Unchecked - Returned to Stock		4					
0110071	Unstable			1	2	1		

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0110071	Will not Calibrate - During Use							3

Comments on Returns:

returns / faults are very very low
0.65% on R-23V for example

Comments on Risks with Returns and Potential Re-work:

no risks - we do not rework, return to supplier

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

design change or rather new products introduce, are tweaks on the existing range.

no major design changes taken place

Comments on Risks with Design Changes:

no risks identified with product 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:

current instructions still valid and suitable

Comments on Risks User Instructions:

no risks with instructions

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
17643	Envitec Oxygen Sensors Labels (Signed scan)	30/09/16
17642	Envitec Oxygen Sensors viamed Labels	30/09/16
9169	No accessory labels	18/10/11

Comments on Labels:

labels updated 2016
still suitable for purpose

Comments on Risks Labels:

no risks with labelling

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
20109	Envitec Oxygen Sensors Risk Assesment	16/05/17
18299	Envitec Oxygen Sensors Product Changes Phase out Oxygen Sensors	19/12/16
18285	Envitec Warranty Terms	16/12/16
18283	Envitec Quality-Warranty General	16/12/16
18144	Envitec Oxygen Sensors Quality Assurance and Agreements	30/11/16
18112	Envitec Oxygen Sensors Transportation and Storage test reports	17/11/16
18110	Envitec Oxygen Sensors Classification rationale..	17/11/16
18108	Envitec Oxygen Sensors Details of Clinical investigations	17/11/16
18106	Envitec Oxygen Sensors Evidence of Usability Human factors asses...	17/11/16
18104	Envitec Oxygen Sensors Results for safety and EMC testing.	17/11/16
18102	Envitec Oxygen Sensors Detailed test results Device verificatio...	17/11/16
18100	Envitec Oxygen Sensors Risk management document for the system	17/11/16
18098	Envitec Oxygen Sensors Manufacturing process	17/11/16
18095	Envitec Oxygen Sensors Design input specification .	17/11/16
18081	Envitec Oxygen Sensors Solutions adopted to fulfil the Essential...	17/11/16
17859	Envitec Oxygen Sensors Location of Documents	09/11/16
17849	MSDS VST 80100XX Series oxygen sensors v1.1	04/11/16
17847	Envitec Oxygen Sensors Material Saftey Data Sheet 2.0.1	04/11/16
17842	MSDS Viamed Oxygen Sensors	04/11/16
17746	Envitec Oxygen Sensors Quality Assurance and Agreements PRODUCT ...	28/10/16
17716	Envitec Oxygen Sensors Product Changes Oxygen sensor review OOM1...	18/10/16
17715	Envitec Oxygen Sensors Product Changes Oxygen sensor review OOM1...	18/10/16
17714	Envitec Oxygen Sensors Product Changes Oxygen sensor review OOM...	18/10/16
17644	Envitec Oxygen Sensors Expected Life of Products UDI dates expla...	30/09/16
17643	Envitec Oxygen Sensors Labels (Signed scan)	30/09/16
17642	Envitec Oxygen Sensors viamed Labels	30/09/16
17622	Specification Datasheet - 0110049	28/09/16
17620	Specification Datasheet - 0110048	28/09/16
17618	Specification Datasheet - 0110043	28/09/16
17615	Envitec Oxygen Sensors Description of Accessories	28/09/16
17613	Envitec Oxygen Sensors medicinal substance human blood derivati...	28/09/16
17611	Envitec Oxygen Sensors Software verification and validation repo...	28/09/16
17609	Envitec Oxygen Sensors Applicability of Machinery Directive 2006...	28/09/16
17607	Envitec Oxygen Sensors Details of significant subcontractors as ...	28/09/16
17606	Envitec Oxygen Sensors Location of responsibilities	28/09/16
17604	Oxygen Sensors Description of Device	28/09/16
17491	Envitec Oxygen Sensors Quality Assurance and Agreements Prices 2...	20/09/16
17481	0110045 Declaration of Compatibility	15/09/16
17436	Envitec Oxygen Sensors Parts List	07/09/16
16790	Envitec Oxygen Sensors Post Market Surveillance	20/04/16

Comments on Document Changes:

documents have been updated showing who has control over files at envitec,
further documents are being updated due to the new mhra stance on obl/virtual manufacturers

Comments on Risks with Document Changes:

no risks identified with document updates

Internal Issues Review

Number of Issues reviewed: 569

Issue ID	Subject
82543	0110019 R-17vi
82544	0110020 R-22Vi
82542	0110018 R-17V
92652	0110020 R-22Vi to order
82545	0110025 R-23Vi
82541	0110039 0110073 R-22VA Sensor Information for Leaflet
85392	0110039 R-22VA 0110073 R-22VA
72838	0110044 packaging and flow diverter
92047	0111275 Oxiquant
92046	0111275 Oxiquant
80358	0111275 to QA
56200	18mm OD flow sensor diverter for R-26MED as used on Stephan F120
92844	200 x 0110020 to order
90012	Additional medical oxygen sensors to promote
90011	Additional medical oxygen sensors to promote
90010	Additional medical oxygen sensors to promote
90009	Additional medical oxygen sensors to promote
90008	Additional medical oxygen sensors to promote
90007	Additional medical oxygen sensors to promote
90006	Additional medical oxygen sensors to promote
90005	Additional medical oxygen sensors to promote
90004	Additional medical oxygen sensors to promote
90003	Additional medical oxygen sensors to promote
90002	Additional medical oxygen sensors to promote
90001	Additional medical oxygen sensors to promote
90000	Additional medical oxygen sensors to promote
89999	Additional medical oxygen sensors to promote
89998	Additional medical oxygen sensors to promote
55659	Atom Incu i Incubator
65435	Atom Incu i Incubator - R-22MED not fitting physically
81933	Atom oxygen sensor 0110039, 0110073
71854	Backorder 00000030 0110043 ORD80377
78138	Backorder 00000030 0120099 ORD82093
72425	Backorder 00000050 0110023 ORD80599
90302	Backorder 00000065 0110023 ORD85162
87943	Backorder 00000065 0110043 ORD84602
93074	Backorder 00000086 0110023 ORD85910
84232	Backorder 00000112 0110023 ORD83587
88720	Backorder 00000112 0110023 ORD84826
92536	Backorder 00000112 0110023 ORD85753
84855	Backorder 00000116 0110071 ORD83769
78351	Backorder 00000123 0110040 ORD82158

Issue ID	Subject
84712	Backorder 00000127 0110071 ORD83707
83038	Backorder 00000128 0110021 ORD83230
90921	Backorder 00000128 0110021 ORD85323
71804	Backorder 00000129 0110023 ORD80382
72205	Backorder 00000150 0110023 ORD80485
70475	Backorder 00000205 0110023 ORD79911
70438	Backorder 00000233 0110023 ORD79923
71379	Backorder 00000233 0110023 ORD80245
85044	Backorder 00000235 0110023 ORD83822
86517	Backorder 00000290 0110040 ORD84213
70856	Backorder 00000333 0110023 ORD80067
81264	Backorder 00000470 0110071 ORD82752
94295	Backorder 00000470 0110071 ORD86175
87139	Backorder 00000500 0110023 ORD84379
84373	Backorder 00000570 0110023 ORD83611
88577	Backorder 00000570 0110023 ORD84770
72625	Backorder 00000620 0110071 ORD80692
79342	Backorder 00000620 0110071 ORD82350
87940	Backorder 00000620 0110071 ORD84598
90565	Backorder 00000620 0110071 ORD85237
74469	Backorder 00000680 0110023 ORD81214
82066	Backorder 00000680 0110023 ORD82961
94664	Backorder 00000680 0110023 ORD86299
72819	Backorder 00000740 0110023 ORD80772
87281	Backorder 00000740 0110023 ORD84422
92199	Backorder 00000740 0110023 ORD85678
88998	Backorder 00000740 0110040 ORD84909
85678	Backorder 00000790 0110071 ORD84011
71121	Backorder 00000860 0110023 ORD80123
71499	Backorder 00000860 0110043 ORD80277
93043	Backorder 00000900 0110040 ORD85884
90832	Backorder 00000980 0110023 ORD85294
91582	Backorder 00000980 0110023 ORD85520
83354	Backorder 00001002 0110040 ORD83331
88988	Backorder 00001002 0110071 ORD84902
75074	Backorder 00001040 0110043 ORD81351
75618	Backorder 00001040 0110043 ORD81489
79347	Backorder 00001040 0110043 ORD82365
91107	Backorder 00001040 0110043 ORD85372
93553	Backorder 00001040 0110043 ORD86047
73415	Backorder 00001045 0110040 ORD80939
92127	Backorder 00001045 0110040 ORD85646
92204	Backorder 00001045 0110040 ORD85685
86418	Backorder 00001060 0110071 ORD84190
72197	Backorder 00001170 0110023 ORD80512

Issue ID	Subject
72420	Backorder 00001170 0110023 ORD80615
85573	Backorder 00001170 0110023 ORD83970
90747	Backorder 00001170 0110071 ORD85274
90073	Backorder 00001320 0110023 ORD85091
78127	Backorder 00001320 0110071 ORD82104
94874	Backorder 00001390 0110040 ORD86316
82144	Backorder 00001390 0110071 ORD82976
70206	Backorder 00001415 0110071 ORD79841
79878	Backorder 00001415 0110071 ORD82472
87769	Backorder 00001415 0110071 ORD84559
88586	Backorder 00001440 0110049 ORD84768
85676	Backorder 00001480 0110023 ORD84008
82539	Backorder 00001521 0110023 ORD83089
92123	Backorder 00001601 0110023 ORD85634
80621	Backorder 00001601 0110040 ORD82629
85680	Backorder 00001601 0110040 ORD84014
84714	Backorder 00001610 0110071 ORD83690
71175	Backorder 00001850 0110023 ORD80135
83866	Backorder 00001850 0110023 ORD83470
92328	Backorder 00001850 0110023 ORD85717
71296	Backorder 00001853 0110023 ORD80212
78126	Backorder 00001853 0110023 ORD82102
74768	Backorder 00001902 0110071 ORD81271
79875	Backorder 00001902 0110071 ORD82468
87389	Backorder 00001902 0110071 ORD84463
90153	Backorder 00001902 0110071 ORD85108
81265	Backorder 00001955 0110023 ORD82756
94396	Backorder 00002020 0110040 ORD86209
77750	Backorder 00002040 0110071 ORD81989
92954	Backorder 00002040 0110071 ORD85858
77659	Backorder 00002080 0110071 ORD81965
81315	Backorder 00002080 0110071 ORD82767
86888	Backorder 00002081 0110021 ORD84318
79005	Backorder 00002081 0110041 ORD82315
81467	Backorder 00002130 0110048 ORD82805
83214	Backorder 00002130 0110048 ORD83305
70480	Backorder 00002152 0110071 ORD79933
85581	Backorder 00002191 0110023 ORD83989
77211	Backorder 00002320 0110071 ORD81902
87941	Backorder 00002320 0110071 ORD84599
90234	Backorder 00002360 0110072 ORD85127
72972	Backorder 00002400 0110043 ORD80816
90486	Backorder 00002420 0110041 ORD85217
70302	Backorder 00002420 0110071 ORD79859
75496	Backorder 00002420 0110071 ORD81453

Issue ID	Subject
81468	Backorder 00002420 0110071 ORD82806
72763	Backorder 00002471 0110043 ORD80729
73413	Backorder 00002500 0110040 ORD80916
82780	Backorder 00002500 0110040 ORD83155
91314	Backorder 00002500 0110040 ORD85446
85584	Backorder 00002500 0110071 ORD83986
91816	Backorder 00002570 0110040 ORD85580
73857	Backorder 00002570 0110071 ORD81024
82623	Backorder 00002570 0110071 ORD83111
72882	Backorder 00002600 0110043 ORD80775
86728	Backorder 00002600 0110043 ORD84260
91258	Backorder 00002600 0110043 ORD85423
72415	Backorder 00002609 0110040 ORD80607
86314	Backorder 00002609 0110040 ORD84166
87507	Backorder 00002609 0110040 ORD84485
70430	Backorder 00002610 0110047 ORD79893
80021	Backorder 00002650 0110048 ORD82497
74565	Backorder 00002690 0110023 ORD81229
77748	Backorder 00002690 0110023 ORD81992
85139	Backorder 00002690 0110023 ORD83839
87839	Backorder 00002690 0110023 ORD84573
72065	Backorder 00002690 0110040 ORD80470
90834	Backorder 00002690 0110043 ORD85289
73128	Backorder 00002950 0110042 ORD80874
85755	Backorder 00003000 0110043 ORD84058
81156	Backorder 00003070 0110071 ORD82712
84737	Backorder 00003220 R212P91 ORD83714
89447	Backorder 00003400 0110042 ORD84973
72966	Backorder 00003450 0110023 ORD80804
84909	Backorder 00003450 0110023 ORD83757
88900	Backorder 00003450 0110023 ORD84881
72627	Backorder 00003450 0110071 ORD80695
91712	Backorder 00003460 0120095 ORD85556
93440	Backorder 00003463 0110023 ORD86007
91041	Backorder 00003490 0110023 ORD85361
79872	Backorder 00003490 0110048 ORD82465
80634	Backorder 00003490 0110048 ORD82635
88581	Backorder 00003500 0110071 ORD84758
91039	Backorder 00003500 0110071 ORD85357
80625	Backorder 00003520 0110040 ORD82622
70380	Backorder 00003560 0110023 ORD79875
71124	Backorder 00003560 0110023 ORD80131
71925	Backorder 00003560 0110023 ORD80399
72200	Backorder 00003560 0110023 ORD80509
78449	Backorder 00003580 0110071 ORD82180

Issue ID	Subject
71436	Backorder 00003640 0110023 ORD80249
71498	Backorder 00003640 0110023 ORD80274
78352	Backorder 00003640 0110023 ORD82131
71698	Backorder 00003640 0110071 ORD80339
76976	Backorder 00003640 0110071 ORD81836
72767	Backorder 00003665 0110040 ORD80734
93874	Backorder 00003665 0110040 ORD86118
71695	Backorder 00003780 0110023 ORD80330
74143	Backorder 00003780 0110023 ORD81118
81469	Backorder 00003780 0110023 ORD82807
84223	Backorder 00003780 0110023 ORD83581
71579	Backorder 00003785 0110023 ORD80307
71789	Backorder 00003785 0110023 ORD80336
81890	Backorder 00003785 0110023 ORD82910
70477	Backorder 00003800 0110023 ORD79926
86404	Backorder 00003800 0110023 ORD84186
87840	Backorder 00003800 0110023 ORD84576
89866	Backorder 00003800 0110023 ORD85062
71965	Backorder 00003940 0110040 ORD80426
74310	Backorder 00003940 0110048 ORD81163
74392	Backorder 00003970 0110043 ORD81187
89780	Backorder 00003970 0110043 ORD85037
82773	Backorder 00003970 0110071 ORD83160
85360	Backorder 00003970 0110071 ORD83925
71855	Backorder 00004040 0110040 ORD80381
89427	Backorder 00004040 0110040 ORD84959
69856	Backorder 00004040 0110048 ORD79740
75361	Backorder 00004040 0110048 ORD81408
77869	Backorder 00004040 0110048 ORD82008
92808	Backorder 00004044 0110048 ORD85829
73753	Backorder 00004080 0110023 ORD80995
93330	Backorder 00004080 0110023 ORD85959
71125	Backorder 00004110 0110023 ORD80137
72507	Backorder 00004127 0110040 ORD80637
75490	Backorder 00004127 0110040 ORD81449
79293	Backorder 00004127 0110040 ORD82360
91108	Backorder 00004127 0110040 ORD85377
93324	Backorder 00004127 0111275 ORD85963
78781	Backorder 00004210 0110040 ORD82257
87684	Backorder 00004300 0110040 ORD84527
71703	Backorder 00004300 0110071 ORD80344
92129	Backorder 00004300 0110071 ORD85650
93421	Backorder 00004400 0110023 ORD85991
93760	Backorder 00004400 0110023 ORD86093
71932	Backorder 00004400 0110040 ORD80419

Issue ID	Subject
83984	Backorder 00004400 0110040 ORD83498
92201	Backorder 00004470 0110043 ORD85681
72778	Backorder 00004507 0110040 ORD80724
75486	Backorder 00004560 0111275 ORD81419
91317	Backorder 00004710 0110023 ORD85453
93651	Backorder 00004710 0110023 ORD86066
75599	Backorder 00004735 0110023 ORD81476
74311	Backorder 00004735 0110043 ORD81156
75359	Backorder 00004735 0110071 ORD81411
75595	Backorder 00004735 0110071 ORD81471
87388	Backorder 00004735 0110071 ORD84458
91701	Backorder 00004735 0110071 ORD85553
72426	Backorder 00004900 0110048 ORD80602
72069	Backorder 00004900 0110071 ORD80468
79520	Backorder 00004900 0110071 ORD82369
80145	Backorder 00004900 0110071 ORD82507
85996	Backorder 00004900 0110071 ORD84117
86624	Backorder 00004900 0110071 ORD84236
90909	Backorder 00004900 0110071 ORD85315
70607	Backorder 00005030 0110023 ORD79955
85143	Backorder 00005030 0110071 ORD83844
70785	Backorder 00005135 0110071 ORD80040
78256	Backorder 00005135 0110071 ORD82140
71127	Backorder 00005140 0110023 ORD80152
78828	Backorder 00005140 0110023 ORD82279
88301	Backorder 00005140 0110023 ORD84692
85582	Backorder 00005240 0110023 ORD83990
91112	Backorder 00005240 0110071 ORD85386
93232	Backorder 00005320 0110043 ORD85940
84445	Backorder 00005380 0110023 ORD83626
71014	Backorder 00005430 0110023 ORD80128
79747	Backorder 00005500 0110023 ORD82429
77134	Backorder 00005520 0110040 ORD81883
82627	Backorder 00005520 0110040 ORD83118
85580	Backorder 00005520 0110040 ORD83988
70297	Backorder 00006003 0110023 ORD79850
90381	Backorder 00006003 0110023 ORD85186
94772	Backorder 00006003 0110023 ORD86304
78181	Backorder 00006027 0110023 ORD82113
87382	Backorder 00006138 0110021 ORD84465
88401	Backorder 00006158 0110023 ORD84707
71806	Backorder 00006158 0110045 ORD80376
75594	Backorder 00006158 0110045 ORD81469
72412	Backorder 00006158 0110071 ORD80595
90401	Backorder 00006175 0110045 ORD85152

Issue ID	Subject
78246	Backorder 00006176 0110049 ORD82125
87280	Backorder 00006257 0110023 ORD84436
73410	Backorder 00006302 0110040 ORD80922
79700	Backorder 00006352 0110023 ORD82421
72506	Backorder 00006356 0110047 ORD80632
91577	Backorder 00006376 0110048 ORD85517
93316	Backorder 00006404 0110048 ORD85951
93079	Backorder 00006676 0110023 ORD85894
73682	Backorder 00006776 0110021 ORD80962
70920	Backorder 00007088 0110049 ORD80050
75379	Backorder 00007138 0110023 ORD81414
84517	Backorder 00007138 0110023 ORD83647
73472	Backorder 00007138 0110043 ORD80958
79818	Backorder 00007138 0110043 ORD81828
78271	Backorder 00007138 0110043 ORD82141
86995	Backorder 00007157 0110023 ORD84343
84362	Backorder 00007356 0110023 ORD83579
74362	Backorder 00007374 0014711 ORD81192
78402	Backorder 00007374 0110017 ORD82172
78403	Backorder 00007374 0110022 ORD82172
76209	Backorder 00007374 0110023 ORD81673
78405	Backorder 00007374 0110040 ORD82172
78406	Backorder 00007374 0110057 ORD82172
78404	Backorder 00007374 2530004 ORD82073
78827	Backorder 00007446 0110560 ORD82275
84366	Backorder 00007461 0110023 ORD83608
76902	Backorder 00007500 0110048 ORD81761
71329	Backorder 00007545 0110023 ORD80014
87855	Backorder 00007586 0110042 ORD84583
94205	Backorder 00007679 0110040 ORD86173
72967	Backorder 00007714 0110045 ORD80802
94298	Backorder 00007758 0110021 ORD86185
71994	Backorder 00007883 0110023 ORD80436
70146	Backorder 00007883 0110044 ORD79815
72521	Backorder 00007883 0110044 ORD80436
81358	Backorder 00007883 0110047 ORD82768
74890	Backorder 00007931 0110048 ORD81297
91503	Backorder 00007976 0110023 ORD85510
73050	Backorder 00012121 0110021 ORD80851
85399	Backorder 00012129 R212P75-001 ORD83942
85138	Backorder 00012132 0110043 ORD83838
87287	Backorder 00012132 0110043 ORD84441
70506	Backorder 00012178 0110023 ORD79945
72206	Backorder 00012178 0110040 ORD80507
83216	Backorder 00012178 0110040 ORD83306

Issue ID	Subject
94398	Backorder 00012178 0110040 ORD86208
72883	Backorder 00012240 0110021 ORD80790
73127	Backorder 00012240 0110021 ORD80873
74146	Backorder 00012240 0110021 ORD81114
75292	Backorder 00012240 0110021 ORD81385
75369	Backorder 00012240 0110021 ORD81412
75994	Backorder 00012240 0110021 ORD81544
79873	Backorder 00012240 0110021 ORD82466
88210	Backorder 00012240 0110021 ORD84653
88982	Backorder 00012240 0110021 ORD84885
89655	Backorder 00012240 0110021 ORD84997
90566	Backorder 00012240 0110021 ORD85238
91315	Backorder 00012240 0110021 ORD85449
92198	Backorder 00012240 0110021 ORD85676
92961	Backorder 00012240 0110021 ORD85861
94662	Backorder 00012240 0110021 ORD86296
74566	Backorder 00012240 0110043 ORD81230
75786	Backorder 00012240 0110043 ORD81544
72927	Backorder 00012240 0110047 ORD80790
88216	Backorder 00012389 0110020 ORD84658
85579	Backorder 00012595 0110043 ORD83981
74770	Backorder 00012605 0110021 ORD81275
72194	Backorder 00012605 0110040 ORD80484
80268	Backorder 00012605 0111275 ORD82561
73850	Backorder 00012812 0110021 ORD81014
86403	Backorder 00012907 0110048 ORD84181
91252	Backorder 00012968 0110019 ORD85418
92626	Backorder 00012968 0110019 ORD85769
94875	Backorder 00012968 0110019 ORD86317
74341	Cross Reference - MOX-3 to MAX-3/R-48V
68959	Discontinued
70267	Document Update Request (611)
82384	Envitec product customization agreement
76906	Incorrect images on 0110021 page
44976	MAX-16 failures - test results
82084	Maxtec O-rings degrading in anaesthetic applications
76990	Missing images in Export Data
82819	MSDS for Viamed Oxygen sensors
74826	Need to order more 0110048.
93368	OEMQA data
81932	Oxygen sensor additions October 2016
81931	Oxygen sensor additions October 2016
81744	Oxygen sensor review OOM102-1 & OOM103-1
81752	Oxygen sensor review OOM103
81751	Oxygen sensor review OOM103

Issue ID	Subject
81750	Oxygen sensor review OOM103
81749	Oxygen sensor review OOM103
81748	Oxygen sensor review OOM103
81761	Oxygen sensor review OOM201 & OOM104
81760	Oxygen sensor review OOM201 & OOM104
81759	Oxygen sensor review OOM201 & OOM104
81758	Oxygen sensor review OOM201 & OOM104
81757	Oxygen sensor review OOM201 & OOM104
78954	Oxygen Sensors - Unique Device Identification & GTIN
82472	P.O. for 0110018, 0110019, 0110020, 0110025
82471	P.O. for 0110018, 0110019, 0110020, 0110025
82470	P.O. for 0110018, 0110019, 0110020, 0110025
82475	P.O. for 0110039 prototype Atom oxygen sensors
82474	P.O. for 0110039 prototype Atom oxygen sensors
82473	P.O. for 0110039 prototype Atom oxygen sensors
85380	Photos/Images 0110018 R-17V Amend Drawing
86847	Photos/Images 0110039 R-22VA 0110073 R-22VA Amend Drawing
70576	POR10688 0110048 //
70575	POR10688 0110048 //
70617	POR10723 0110021 //
70533	POR10723 0110021 //
70624	POR10724 0110040 //
70529	POR10724 0110040 //
70625	POR10724 0110043 //
70530	POR10724 0110043 //
70626	POR10724 0110044 //
70531	POR10724 0110044 //
71298	POR10742 0110049 //
71201	POR10742 0110049 //
71390	POR10745 0110021 //
71738	POR10745 0110021 24/06/2016
71796	POR10755 0110040 //
71879	POR10755 0110040 21/06/2016
71797	POR10755 0110041 //
71880	POR10755 0110041 21/06/2016
71882	POR10757 0110045 //
71999	POR10757 0110045 02/06/2016
73277	POR10798 0110021 //
73287	POR10798 0110021 26/07/2016
73278	POR10798 0110040 //
73288	POR10798 0110040 26/07/2016
73279	POR10798 0110043 //
73289	POR10798 0110043 26/07/2016
73280	POR10798 0110045 //
73290	POR10798 0110045 26/07/2016

Issue ID	Subject
73319	POR10799 0110023 //
73281	POR10799 0110023 //
73926	POR10812 0110021 //
73802	POR10812 0110021 //
75002	POR10835 0110048 //
74895	POR10835 0110048 //
74938	POR10840 0110021 //
75102	POR10840 0110021 17/08/2016
74939	POR10840 0110048 //
75103	POR10840 0110048 17/08/2016
75143	POR10844 0110043 //
75246	POR10844 0110043 18/08/2016
75144	POR10844 0110047 //
75247	POR10844 0110047 18/08/2016
75684	POR10861 0111275 //
75907	POR10861 0111275 09/08/2016
76987	POR10891 0110021 //
76828	POR10891 0110021 //
76988	POR10891 0110041 //
76829	POR10891 0110041 //
76989	POR10891 0111275 //
76830	POR10891 0111275 //
78556	POR10928 0110023 //
78495	POR10928 0110023 //
78557	POR10928 0110040 //
78496	POR10928 0110040 //
78558	POR10928 0110045 //
78497	POR10928 0110045 //
78559	POR10928 0110049 //
78498	POR10928 0110049 //
78872	POR10936 0110040 //
79056	POR10936 0110040 26/09/2016
78873	POR10936 0110043 //
79057	POR10936 0110043 26/09/2016
78874	POR10936 0110047 //
79058	POR10936 0110047 26/09/2016
78875	POR10936 0110560 //
79059	POR10936 0110560 26/09/2016
79464	POR10956 0110021 //
79396	POR10956 0110021 //
81402	POR10976 0110021 //
81399	POR10976 0110021 //
80654	POR10976 0110021 //
81403	POR10976 0110040 //
81400	POR10976 0110040 //

Issue ID	Subject
80655	POR10976 0110040 //
81404	POR10976 0110048 //
81401	POR10976 0110048 //
80656	POR10976 0110048 //
82977	POR11024 0110018 //
82790	POR11024 0110018 //
82978	POR11024 0110019 //
82791	POR11024 0110019 //
82979	POR11024 0110020 //
82792	POR11024 0110020 //
82980	POR11024 0110025 //
82793	POR11024 0110025 //
84301	POR11025 0110039 //
83242	POR11025 0110039 //
82789	POR11025 0110039 //
83544	POR11039 0110021 //
83267	POR11039 0110021 //
83545	POR11039 0110023 //
83268	POR11039 0110023 //
83546	POR11039 0110040 //
83269	POR11039 0110040 //
83547	POR11039 0110047 //
83270	POR11039 0110047 //
83758	POR11045 0110023 //
83522	POR11045 0110023 //
83759	POR11045 0110040 //
83523	POR11045 0110040 //
83760	POR11045 0110043 //
83524	POR11045 0110043 //
83761	POR11045 0110047 //
83525	POR11045 0110047 //
85369	POR11067 R212P91 //
85307	POR11067 R212P91 //
84744	POR11067 R212P91 //
86430	POR11068 0110021 //
84745	POR11068 0110021 //
86554	POR11099 0110041 //
86422	POR11099 0110041 //
86555	POR11099 0110043 //
86423	POR11099 0110043 //
86556	POR11099 0110048 //
86424	POR11099 0110048 //
86557	POR11099 0110049 //
86425	POR11099 0110049 //
88084	POR11100 R212P75-001 //

Issue ID	Subject
87313	POR11100 R212P75-001 //
86903	POR11100 R212P75-001 //
86543	POR11100 R212P75-001 //
88085	POR11100 R212P91 //
87314	POR11100 R212P91 //
86904	POR11100 R212P91 //
86544	POR11100 R212P91 //
88086	POR11100 R213P42 //
87315	POR11100 R213P42 //
86905	POR11100 R213P42 //
86545	POR11100 R213P42 //
86991	POR11112 0110021 //
86839	POR11112 0110021 //
86992	POR11112 0110560 //
86840	POR11112 0110560 //
88078	POR11132 0110042 //
87877	POR11132 0110042 //
88075	POR11137 0110023 //
87949	POR11137 0110023 //
88076	POR11137 0110040 //
87950	POR11137 0110040 //
88077	POR11137 0110043 //
87951	POR11137 0110043 //
88927	POR11154 0110049 //
88723	POR11154 0110049 //
88724	POR11155 0110021 //
89435	POR11164 0110019 //
89434	POR11164 0110019 //
89069	POR11164 0110019 //
90071	POR11164 0110019 Have Been Delivered or Cancelled in Opera
90511	POR11184 0110042 //
90396	POR11184 0110042 //
90512	POR11184 0110045 //
90397	POR11184 0110045 //
91504	POR11199 0110021 //
91359	POR11199 0110021 //
91517	POR11206 0111275 //
91361	POR11206 0111275 //
92372	POR11218 0110048 //
91611	POR11218 0110048 //
92740	POR11229 0111275 //
92349	POR11229 0111275 //
92741	POR11238 0110020 //
92681	POR11238 0110020 //
92973	POR11241 0110020 //

Issue ID	Subject
93347	POR11243 0120095 //
93343	POR11243 0120095 //
92976	POR11243 0120095 //
93056	POR11244 0110040 //
92979	POR11244 0110040 //
93057	POR11244 0110048 //
92980	POR11244 0110048 //
93058	POR11244 0110049 //
92981	POR11244 0110049 //
94043	POR11258 0110023 //
93803	POR11258 0110023 //
94348	POR11261 0110019 //
94349	POR11261 0110023 //
94350	POR11261 0110040 //
94351	POR11261 0110041 //
94352	POR11261 0110043 //
94353	POR11261 0110045 //
94354	POR11261 0110048 //
87151	Price List Oxygen Monitoring Catalogue
87150	Price List Oxygen Monitoring Catalogue
39609	Problem with R-42V replacement sensor for Stephan
76219	R-22MEDV premature failures
87162	R-22Vi matched pairs
71872	Sunshine Biomedical Solutions
79279	Teledyne Sales
72000	Update serial Number
70248	Urgent oxygen sensor order to go out today
70247	Urgent oxygen sensor order to go out today
70245	Urgent oxygen sensor order to go out today
88311	VM3COP37.55 R-30V Oxygen Sensor 0110030
93557	Web Site Question ID 1037
82379	Web Site Question ID 971

Comments on Issues:

no risks 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 :

Oxygen sensors are a component of oxygen monitors and monitoring devices,
there are no clinical reports to be found on the oxygen sensor part.

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 :

Oxygen sensors are a component of oxygen monitors and monitoring devices,
there are no FDA reports to be found on the oxygen sensor part.