



26/Oct/2012

Post market Surveillance and Risk Assessment Re-evaluation

Envitec Oxygen Sensors
Viamed OBL product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
User Manuals Review
Labels Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 26 / 10 / 12

Stock References Reviewed

Stock Reference	Description
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.
8010003	Oxygen Sensor - VR1700

Comments on Stock references review:

List is complete.

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0110023	Oxygen sensor R-23V	00007282	EnviteC-Wismar GmbH	B
0110040	Oxygen sensor R-30V	00007282	EnviteC-Wismar GmbH	B
0110041	Oxygen sensor R-41V	00007282	EnviteC-Wismar GmbH	B
0110042	Oxygen sensor R-42V	00007282	EnviteC-Wismar GmbH	B
0110043	Oxygen sensor R-43V. Pack of 2 sensors.	00007282	EnviteC-Wismar GmbH	B
0110044	Oxygen sensor R-44V.	00007282	EnviteC-Wismar GmbH	B
0110045	Oxygen sensor R-45V.	00007282	EnviteC-Wismar GmbH	B
0110047	Oxygen sensor R-47V.	00007282	EnviteC-Wismar GmbH	B
8010003	Oxygen Sensor - VR1700	00007282	EnviteC-Wismar GmbH	B
0110023	Oxygen sensor R-23V	00009147	Teledyne Analytical Instrument	A

Comments on Suppliers:

Teledyne not the Supplier anymore of these sensors

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0110023	Oxygen sensor R-23V	845	753	930	898	1139	1257	970
0110040	Oxygen sensor R-30V					77	239	221
0110041	Oxygen sensor R-41V					5	14	18
0110042	Oxygen sensor R-42V					4	29	33
0110043	Oxygen sensor R-43V. Pack of 2 sensors.					67	259	182
0110044	Oxygen sensor R-44V.						10	3
0110045	Oxygen sensor R-45V.					3	13	
0110046	Oxygen sensor R-46V.							
0110047	Oxygen sensor R-47V.						39	37
8010003	Oxygen Sensor - VR1700							

Comments on Sales Information:

Sales appears to have dropped for these sensors.

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
AL Algeria						[X]	[X]
AU Austria							
B Belgium	[X]			[X]		[X]	[X]
BA State of Bahrain				[X]			[X]
BRA Brazil						[X]	
BU Bulgaria					[X]	[X]	[X]
C China	[X]	[X]	[X]	[X]	[X]	[X]	
CH Chile							
CY Cyprus							[X]
DE Denmark			[X]	[X]	[X]	[X]	[X]
EG Egypt						[X]	
F France	[X]						
FI Finland	[X]	[X]					
G Germany						[X]	
GEO Georgia						[X]	
GR Greece	[X]	[X]			[X]	[X]	[X]
IN India			[X]	[X]	[X]	[X]	
IRE Ireland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
IS Israel	[X]	[X]	[X]	[X]		[X]	[X]
IT Italy	[X]	[X]	[X]	[X]	[X]	[X]	
JO Jordan			[X]				[X]
KU Kuwait							
LA Latvia					[X]		[X]
LEB Lebanon			[X]	[X]	[X]	[X]	[X]
LI Lithuania						[X]	[X]
LIB Libya							[X]
MA Malaysia		[X]	[X]			[X]	[X]
MO Morocco		[X]	[X]	[X]	[X]	[X]	[X]
NE Netherlands							
NG Nigera			[X]				[X]
NO Norway							
P Poland						[X]	[X]
PH Philippines						[X]	
PO Portugal		[X]	[X]				
Q Qatar				[X]			
RO Romania				[X]	[X]		
SA South Africa				[X]	[X]	[X]	
SAU Saudi Arabia				[X]		[X]	[X]
SER Serbia				[X]	[X]	[X]	[X]
SI Singapore							[X]
SL Slovenia							[X]
SP Spain	[X]	[X]	[X]		[X]		
SRI Sri Lanka						[X]	
SW Sweden		[X]					
SWI Switzerland						[X]	
SY Syria							

Country	2006	2007	2008	2009	2010	2011	2012
T Turkey					[X]	[X]	
TH Thailand	[X]	[X]	[X]		[X]		
UAE U.A.E.					[X]	[X]	
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA U.S.A.					[X]		

Comments on Sales to Countries:

CY Cyprus , SI Singapore are new countries for these sensors,

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.
8010003 Oxygen Sensor - VR1700

We seem to have lost sales to :

UAE U.A.E. T Turkey SWI Switzerland SRI Sri Lanka SA South Africa RO Romania PH Philippines IN India GEO Georgia EG Egypt C China BRA Brazil
Follow up Issue #39742

Comments on Risks with Sales to Countries:

No new risks identified with the new countries

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
0110023	Bubble in electrolyte							2
0110023	Fluctuating o/p - During Use						1	2
0110023	High output - During Use		2					
0110023	High output - will not calibrate						1	
0110023	Low Output			1				
0110023	Low output - During Use		2					
0110023	No Fault Return to Stock				1			
0110023	No output					2		
0110023	No output - During Use	2						
0110023	Non Linear - During Use	1						
0110023	Offset failure					1		
0110023	Rising output - During Use		1					
0110023	Unstable							1
0110023	Will not Calibrate - During Use	3			1			
0110040	Fluctuating o/p - During Use							1
0110042	Cable fault							3
0110043	Bubble in electrolyte							2
0110043	End of life							3
0110043	Low Output						1	
0110045	Calibration failed							1
0110047	Calibration failed							3
0110047	Fluctuating o/p - During Use							1
8010003	Connector - corrosion							3
8010003	Low output during dive						1	
8010003	No Fault Found						2	6

Comments on Returns:

Very low numbers of returns,

Comments on Risks with Returns and Potential Re-work:

No re-work so no risks

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes

Comments on Risks with Design Changes:

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
9166	NO user instructions required	18/10/11

Comments on User Instructions:

No user instructions supplied

Comments on Risks User Instructions:

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9500	Envitec Oxygen Sensor R-23V Labels	18/10/11
9169	No accessory labels	18/10/11

Comments on Labels:

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

Updated supplier certificates

Comments on Risks with Document Changes:

no risks with updated documentation

Review of Issues

Number of Issues reviewed: 13

Issue ID	Subject
32137	Returned Items SOR477
31972	Initial stock level alarms - medical oxugen sensors
33819	R-47V failures
30750	Sensor Cross reference missing 0110043
34120	Declaration of Conformity - R-23V
34119	Declaration of Conformity - R-23V
33417	Document Update Request
10293	R-45V for Viasys Avea
39742	PMS Viamed OBL product Envitec Oxygen Sensors Sales Countries
37862	QA Non Urgent Auto Suggestion List
32594	Scanning Error
34783	0110023 output
35570	0110043 Output edits

Comments on Issues:

No comments on Issues raised

Comments on Risks with Issues:

no risks found in the Issues system

Review of online clinical reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

Research Fellow in Clinical Pulmonary Physiology — Physiology ...

www.dpag.ox.ac.uk › About Us › Job Opportunities 1 May 2012 - We are seeking a Research Fellow to organise and deliver clinical studies in Pulmonary ... that there is a strong interplay between iron status and oxygen sensing. ... team; presentation of results and contribution to trial reports and publications.

Why not the liver instead of the kidney?

bloodjournal.hematologylibrary.org/content/120/9/1760.full by J Fandrey - 2012 - Related articles

30 Aug 2012 - ... siRNA targeting cellular oxygen sensors according to the report by Querbes et ... very successful treatment of this anemia. 8 Recently, first clinical experiences ...

iVent101 Life-Support Ventilator - gehealthcare.co.uk

www3.gehealthcare.co.uk/.../iVent101_Life-Support_Ventilat... 7 Sep 2012 - Get powerful clinical performance in a robust yet accessible package. ... Volume limit reached; Emergency backup; AC power disconnect; O2 sensor worn out

...

PROFILE- Breathing power into the cell - Publicservice.co.uk

www.publicservice.co.uk/article.asp?publication...id... 5 Jul 2012 - The cellular and biological processes that rely on oxygen depend on the ability ... and translational questions in the oxygen sensing and hypoxia signalling arena. ... tumour cells and inhibit tumour progression in pre-clinical models (see Fig.

Hearing Red: Innovative Israeli Blood Flow Sensor ... - GE Reports

www.gereports.com/hearing-red/ 28 Aug 2012 - Hearing Red: Innovative Israeli Blood Flow Sensor Start-Up Gets Investment from ... Maintaining adequate blood flow and oxygenation are primary clinical goals ...

Loss of the Oxygen Sensor PHD3 Enhances the Innate Immune ...

www.jimmunol.org/content/early/.../jimmunol.1103471.full by J Kiss - 2012 - Cited by 1 - Related articles

11 Jul 2012 - concluded that impairment of PHD3 enzyme function aggravates the clinical course of abdominal sepsis novel function of the PHD3 oxygen sensor in the innate immune reports (6, 7)] but even further increased upon interference with ...

INTELLiVENT-ASV: Hamilton Medical - Intelligent ventilation

www.hamilton-medical.com/.../intellivent-asv.html?tx...it 29 Jun 2012 - Today, conventional mechanical ventilation still requires clinical expertise and ... decides on the level of oxygen therapy; The reliable noninvasive sensors for ...

In-Vivo Oxygen Uptake into the Human Cornea - Investigative ...

www.iovs.org/content/early/2012/07/.../iovs.12-10059.full.pdf by SC Takatori - 2012 - Cited by 2 - Related articles

26 Jul 2012 - however, theoretical prediction may not faithfully represent clinical response. ... In this time period, the polarographic-oxygen-sensor (POS) signal does not for closed eye in Figure 4), we do not report oxygen-uptake results for the closed ...

[PDF]

Optical oxygen sensor based on fluorescence change of pyrene-1 ...

144.206.159.178/ft/38/72927/1247514.pdf File Format: PDF/Adobe Acrobat - Quick View

by Y Fujiwara - 2002 - Cited by 23 - Related articles

30 Nov 2011 - Keywords: Pyrene; Chemisorption film; Fluorescence; Optical oxygen sensor. 1. ... important in various fields of chemical, clinical anal- ous reports [6–12].

Oxygen Sensor and A/C Issue - HondaSUV Forums - Discussion forum ...

www.hondasuv.com › ... › CR-V::Clinical RoundsShare

11 posts - 6 authors - 6 Jun

Oxygen Sensor and A/C Issue CR-V::Clinical Rounds. ... NOW, I can report the \$22 Universal 4 wire O2 sensor does not work. The computer tells me so.

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 :

Only FDA report found was dealing with MRI problem more to do with checking the sensors once a year.

Safety Equipment

Oxygen Sensor: During MRI quench and cryogen filling operations, there is a potential for cryogens to be released into the MRI room which can displace the oxygen in the room. To alert occupants of a potential oxygen deficiency, oxygen sensors are installed in all MRI areas. Oxygen sensors must remain on at all times. Staff responsible for the supervision of the MRI equipment must ensure oxygen sensors are on and operating at all times. When oxygen sensors are malfunctioning or need to be removed for maintenance temporary oxygen sensors must be in place.