



21/Nov/2012

Post market Surveillance and Risk Assessment Re-evaluation

Pulse Oximetry Sensors 4000 Series
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 21 / 11 / 12

Stock References Reviewed

Stock Reference	Description
0014895	Pulse Oximetry Extension Cable 1.2 m
0014896	Pulse Oximetry Extension Cable 2.4 m
0014901	Disposable SpO2 Sensors - Adult.
0014902	Disposable SpO2 Sensors - Paediatric.
0014903	Disposable SpO2 Sensors - Infant.
0014904	Disposable SpO2 Sensors - Neonatal.
0014905	Disposable SpO2 Sensors - Adult.
0014906	Disposable SpO2 Sensors - Paediatric.
0014909	Disposable SpO2 Sensors - Adult.
0014910	Disposable SpO2 Sensors - Paediatric.
0014911	Disposable SpO2 Sensors - Infant.
0014912	Disposable SpO2 Sensors - Neonatal.
0014913	Disposable SpO2 Sensors - Adult.
0014914	Disposable SpO2 Sensors - Paediatric.
0014915	Disposable SpO2 Sensors - Infant.
0014916	Disposable SpO2 Sensors - Neonatal.
0014917	Disposable SpO2 Sensors - Adult.
0014918	Disposable SpO2 Sensors - Paediatric.
0014921	Disposable SpO2 Sensors - Adult.
0014922	Disposable SpO2 Sensors - Paediatric.
0014923	Disposable SpO2 Sensors - Infant.
0014924	Disposable SpO2 Sensors - Neonatal.
0014925	Disposable SpO2 Sensors - Adult.
0014926	Disposable SpO2 Sensors - Paediatric.
0014927	Disposable SpO2 Sensors - Infant.
0014928	Disposable SpO2 Sensors - Neonatal.
0014929	Disposable SpO2 Sensors - Adult.
0014930	Disposable SpO2 Sensors - Paediatric.
0014933	Disposable SpO2 Sensors - Adult.
0014934	Disposable SpO2 Sensors - Paediatric.
0014935	Disposable SpO2 Sensors - Infant.
0014936	Disposable SpO2 Sensors - Neonatal.
0014937	Disposable SpO2 Sensors - Adult.
0014938	Disposable SpO2 Sensors - Paediatric.
0014939	Disposable SpO2 Sensors - Infant.
0014940	Disposable SpO2 Sensors - Neonatal.
0014941	Disposable SpO2 Sensors - Adult.
0014942	Disposable SpO2 Sensors - Paediatric.
0014945	Disposable SpO2 Sensors - Adult.
0014946	Disposable SpO2 Sensors - Paediatric.
0014947	Disposable SpO2 Sensors - Infant.
0014948	Disposable SpO2 Sensors - Neonatal.
0014949	Disposable SpO2 Sensors - Adult.
0014950	Disposable SpO2 Sensors - Paediatric.
0014951	Disposable SpO2 Sensors - Infant.

Stock Reference	Description
0014952	Disposable SpO2 Sensors - Neonatal.
0014953	Disposable SpO2 Sensors - Adult.
0014954	Disposable SpO2 Sensors - Paediatric.
0014957	Disposable SpO2 Sensors - Adult.
0014958	Disposable SpO2 Sensors - Paediatric.
0014959	Disposable SpO2 Sensors - Infant.
0014960	Disposable SpO2 Sensors - Neonatal.
0014961	Disposable SpO2 Sensors - Adult.
0014962	Disposable SpO2 Sensors - Paediatric.
0014963	Disposable SpO2 Sensors - Infant.
0014964	Disposable SpO2 Sensors - Neonatal.
0014965	Disposable SpO2 Sensors - Adult.
0014966	Disposable SpO2 Sensors - Paediatric.
0014969	Disposable SpO2 Sensors - Adult.
0014970	Disposable SpO2 Sensors - Paediatric.
0014971	Disposable SpO2 Sensors - Infant.
0014972	Disposable SpO2 Sensors - Neonatal.
0014973	Disposable SpO2 Sensors - Adult.
0014974	Disposable SpO2 Sensors - Paediatric.
0014975	Disposable SpO2 Sensors - Infant.
0014976	Disposable SpO2 Sensors - Neonatal.
0014977	Disposable SpO2 Sensors - Adult.
0014978	Disposable SpO2 Sensors - Paediatric.
0014981	Disposable SpO2 Sensors - Adult.
0014982	Disposable SpO2 Sensors - Paediatric.
0014983	Disposable SpO2 Sensors - Infant.
0014984	Disposable SpO2 Sensors - Neonatal.
0014985	Disposable SpO2 Sensors - Adult.
0014986	Disposable SpO2 Sensors - Paediatric.
0014987	Disposable SpO2 Sensors - Infant.
0014988	Disposable SpO2 Sensors - Neonatal.
0014989	Disposable SpO2 Sensors - Adult.
0014990	Disposable SpO2 Sensors - Paediatric.
0014993	Disposable SpO2 Sensors - Adult.
0014994	Disposable SpO2 Sensors - Paediatric.
0014995	Disposable SpO2 Sensors - Infant.
0014996	Disposable SpO2 Sensors - Neonatal.

Comments on Stock references review:

part numbers upto date

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0014901	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	B
0014902	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	B
0014903	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	B
0014904	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	B
0014905	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	B
0014906	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	B
0014909	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	B
0014910	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	B
0014911	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	B
0014912	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	B
0014925	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	B
0014926	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	B
0014927	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	B
0014928	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	B
0014957	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	B
0014958	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	B
0014959	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	B
0014960	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	B
0014895	Pulse Oximetry Extension Cable 1.2 m	00009300	Bluepoint Medical	A
0014896	Pulse Oximetry Extension Cable 2.4 m	00009300	Bluepoint Medical	A
0014901	Disposable SpO2 Sensors - Adult.	00009300	Bluepoint Medical	A
0014902	Disposable SpO2 Sensors - Paediatric.	00009300	Bluepoint Medical	A
0014903	Disposable SpO2 Sensors - Infant.	00009300	Bluepoint Medical	A
0014904	Disposable SpO2 Sensors - Neonatal.	00009300	Bluepoint Medical	A
0014905	Disposable SpO2 Sensors - Adult.	00009300	Bluepoint Medical	A
0014906	Disposable SpO2 Sensors - Paediatric.	00009300	Bluepoint Medical	A
0014909	Disposable SpO2 Sensors - Adult.	00009300	Bluepoint Medical	A
0014910	Disposable SpO2 Sensors - Paediatric.	00009300	Bluepoint Medical	A
0014911	Disposable SpO2 Sensors - Infant.	00009300	Bluepoint Medical	A
0014912	Disposable SpO2 Sensors - Neonatal.	00009300	Bluepoint Medical	A
0014923	Disposable SpO2 Sensors - Infant.	00009300	Bluepoint Medical	A
0014924	Disposable SpO2 Sensors - Neonatal.	00009300	Bluepoint Medical	A
0014940	Disposable SpO2 Sensors - Neonatal.	00009300	Bluepoint Medical	A
0014957	Disposable SpO2 Sensors - Adult.	00009300	Bluepoint Medical	A
0014958	Disposable SpO2 Sensors - Paediatric.	00009300	Bluepoint Medical	A
0014959	Disposable SpO2 Sensors - Infant.	00009300	Bluepoint Medical	A
0014964	Disposable SpO2 Sensors - Neonatal.	00009300	Bluepoint Medical	A
0014990	Disposable SpO2 Sensors - Paediatric.	00009300	Bluepoint Medical	A
0014993	Disposable SpO2 Sensors - Adult.	00009300	Bluepoint Medical	A
0014994	Disposable SpO2 Sensors - Paediatric.	00009300	Bluepoint Medical	A
0014995	Disposable SpO2 Sensors - Infant.	00009300	Bluepoint Medical	A
0014996	Disposable SpO2 Sensors - Neonatal.	00009300	Bluepoint Medical	A

Comments on Suppliers:

supplier information upto date

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0014895	Pulse Oximetry Extension Cable 1.2 m			8	7	8	11	26
0014896	Pulse Oximetry Extension Cable 2.4 m				1	4	4	3
0014901	Disposable SpO2 Sensors - Adult.			3	11	65	51	17
0014902	Disposable SpO2 Sensors - Paediatric.			3	3	13	10	15
0014903	Disposable SpO2 Sensors - Infant.			3	6	6	8	
0014904	Disposable SpO2 Sensors - Neonatal.			54	77	68	43	18
0014905	Disposable SpO2 Sensors - Adult.			36	19	20	50	49
0014906	Disposable SpO2 Sensors - Paediatric.			113	182	178	22	49
0014909	Disposable SpO2 Sensors - Adult.			10	17	17	21	
0014910	Disposable SpO2 Sensors - Paediatric.			4	9	23	12	5
0014911	Disposable SpO2 Sensors - Infant.			9	6	26	40	25
0014912	Disposable SpO2 Sensors - Neonatal.			106	219	19	146	201
0014913	Disposable SpO2 Sensors - Adult.							
0014914	Disposable SpO2 Sensors - Paediatric.							
0014915	Disposable SpO2 Sensors - Infant.							
0014916	Disposable SpO2 Sensors - Neonatal.							
0014917	Disposable SpO2 Sensors - Adult.							
0014918	Disposable SpO2 Sensors - Paediatric.							
0014921	Disposable SpO2 Sensors - Adult.							
0014922	Disposable SpO2 Sensors - Paediatric.							
0014923	Disposable SpO2 Sensors - Infant.				1			
0014924	Disposable SpO2 Sensors - Neonatal.				7	16	1	2
0014925	Disposable SpO2 Sensors - Adult.			1	2	3		6
0014926	Disposable SpO2 Sensors - Paediatric.				2			
0014927	Disposable SpO2 Sensors - Infant.							
0014928	Disposable SpO2 Sensors - Neonatal.			1	3	1		
0014929	Disposable SpO2 Sensors - Adult.							
0014930	Disposable SpO2 Sensors - Paediatric.							
0014933	Disposable SpO2 Sensors - Adult.							
0014934	Disposable SpO2 Sensors - Paediatric.							
0014935	Disposable SpO2 Sensors - Infant.							
0014936	Disposable SpO2 Sensors - Neonatal.							
0014937	Disposable SpO2 Sensors - Adult.							
0014938	Disposable SpO2 Sensors - Paediatric.							
0014939	Disposable SpO2 Sensors - Infant.							
0014940	Disposable SpO2 Sensors - Neonatal.							4
0014941	Disposable SpO2 Sensors - Adult.							
0014942	Disposable SpO2 Sensors - Paediatric.							
0014945	Disposable SpO2 Sensors - Adult.							
0014946	Disposable SpO2 Sensors - Paediatric.							
0014947	Disposable SpO2 Sensors - Infant.							
0014948	Disposable SpO2 Sensors - Neonatal.							
0014949	Disposable SpO2 Sensors - Adult.							
0014950	Disposable SpO2 Sensors - Paediatric.							
0014951	Disposable SpO2 Sensors - Infant.							
0014952	Disposable SpO2 Sensors - Neonatal.							

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0014953	Disposable SpO2 Sensors - Adult.							
0014954	Disposable SpO2 Sensors - Paediatric.							
0014957	Disposable SpO2 Sensors - Adult.				5	3	8	4
0014958	Disposable SpO2 Sensors - Paediatric.				10	10	10	16
0014959	Disposable SpO2 Sensors - Infant.				16	7	7	24
0014960	Disposable SpO2 Sensors - Neonatal.			1	1		5	14
0014961	Disposable SpO2 Sensors - Adult.							
0014962	Disposable SpO2 Sensors - Paediatric.							
0014963	Disposable SpO2 Sensors - Infant.							
0014964	Disposable SpO2 Sensors - Neonatal.						5	3
0014965	Disposable SpO2 Sensors - Adult.							
0014966	Disposable SpO2 Sensors - Paediatric.							
0014969	Disposable SpO2 Sensors - Adult.							
0014970	Disposable SpO2 Sensors - Paediatric.							
0014971	Disposable SpO2 Sensors - Infant.							
0014972	Disposable SpO2 Sensors - Neonatal.					1	1	
0014973	Disposable SpO2 Sensors - Adult.							
0014974	Disposable SpO2 Sensors - Paediatric.							
0014975	Disposable SpO2 Sensors - Infant.							
0014976	Disposable SpO2 Sensors - Neonatal.							
0014977	Disposable SpO2 Sensors - Adult.							
0014978	Disposable SpO2 Sensors - Paediatric.							
0014981	Disposable SpO2 Sensors - Adult.							
0014982	Disposable SpO2 Sensors - Paediatric.							
0014983	Disposable SpO2 Sensors - Infant.							
0014984	Disposable SpO2 Sensors - Neonatal.							
0014985	Disposable SpO2 Sensors - Adult.							
0014986	Disposable SpO2 Sensors - Paediatric.							
0014987	Disposable SpO2 Sensors - Infant.							
0014988	Disposable SpO2 Sensors - Neonatal.							
0014989	Disposable SpO2 Sensors - Adult.						1	
0014990	Disposable SpO2 Sensors - Paediatric.						1	
0014993	Disposable SpO2 Sensors - Adult.						2	
0014994	Disposable SpO2 Sensors - Paediatric.				1	3	3	
0014995	Disposable SpO2 Sensors - Infant.				1	1	4	5
0014996	Disposable SpO2 Sensors - Neonatal.				2	6	17	28

Comments on Sales Information:

units still selling

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
B Belgium					[X]	[X]	[X]
CH Chile				[X]			
CZ Czech Republic			[X]	[X]	[X]	[X]	[X]
ES Estonia						[X]	
FI Finland					[X]	[X]	[X]
G Germany			[X]		[X]	[X]	[X]
GR Greece				[X]	[X]	[X]	[X]
IN India			[X]	[X]			
IRE Ireland			[X]	[X]	[X]	[X]	[X]
JO Jordan							[X]
LEB Lebanon			[X]	[X]			[X]
NE Netherlands							[X]
NG Nigera					[X]		
NO Norway				[X]	[X]		
P Poland				[X]			
PO Portugal			[X]	[X]	[X]	[X]	[X]
SAU Saudi Arabia			[X]	[X]		[X]	[X]
SP Spain			[X]	[X]	[X]	[X]	[X]
SW Sweden						[X]	[X]
T Turkey			[X]	[X]		[X]	[X]
TH Thailand				[X]			
UAE U A E							[X]
UAE U.A.E.				[X]	[X]	[X]	
UK United Kingdom			[X]	[X]	[X]	[X]	[X]
VI Vietnam							[X]

Comments on Sales to Countries:

Vietnam and Netherland and UAE and finall jordan are new countries.

Comments on Risks with Sales to Countries:

no forseeable risks with new countries

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
0014909	No Fault Return to Stock							
0014910	No Fault Return to Stock							
0014911	No Fault Return to Stock							

Comments on Returns:

no faults at all logged

Comments on Risks with Returns and Potential Re-work:

n/a

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

n/a

Comments on Risks with Design Changes:

n/a

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
3539	Pulse Oximeter Sensors BPM Instructions for Use / User Manual ...	28/03/08
3538	Pulse Oximeter Sensors BPM Instructions for Use / User Manual ...	28/03/08
3537	4000 Series SpO2 Sensors Disposable Sensors User Instructions	28/03/08

Comments on User Instructions:

manuals still fit for purpose

Comments on Risks User Instructions:

n/a/

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
11735	Pulse Oximetry Extension Cable 0014896 Dum Bell Label	27/03/12
11734	Pulse Oximetry Extension Cable 0014895 Dum Bell Label	27/03/12
6694	Pulse Oximetry Sensors 4000 Series Labels probe label	13/11/09
6693	Pulse Oximetry Sensors 4000 Series Labels pkg label	13/11/09

Comments on Labels:

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

cad drawing and certificate updates

Comments on Risks with Document Changes:

no.

Review of Issues

Number of Issues reviewed: 11

Issue ID	Subject
38481	Courier Cost - UAE
38480	Courier Cost - UAE
37599	Cime Group - Weight & Dimensions
37598	Cime Group - Weight & Dimensions
33521	Returned Items SOR481
33351	Returned Items SOR459
35585	Additions to Website Required
36336	0034996 - Disp Sp02 Sensor
34009	Bluepoint Order POR08286
38960	Peto / GHX spreadsheet corrections
35779	Queen Mary Hospital

Comments on Issues:

Nothing found of relevance in the issues system

Comments on Risks with Issues:

no risk identified in the issue 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 :

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 :