



24/Oct/2011

Pulse Oximetry Sensors 4

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
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 24 / 10 / 11

Stock References Reviewed

Stock Reference	Description
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.
0014952	Disposable SpO2 Sensors - Neonatal.
0014953	Disposable SpO2 Sensors - Adult.

Stock Reference	Description
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:

No new Product line to add

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
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
0014957	Disposable SpO2 Sensors - Adult.	00009300	Bluepoint Medical	A
0014958	Disposable SpO2 Sensors - Paediatric.	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:

No comments on supplier

Sales Information

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
0014901	Disposable SpO2 Sensors - Adult.				3	11	65	41
0014902	Disposable SpO2 Sensors - Paediatric.				3	3	13	10
0014903	Disposable SpO2 Sensors - Infant.				3	6	6	8
0014904	Disposable SpO2 Sensors - Neonatal.				54	77	68	43
0014905	Disposable SpO2 Sensors - Adult.				36	19	20	50
0014906	Disposable SpO2 Sensors - Paediatric.				113	182	178	22
0014909	Disposable SpO2 Sensors - Adult.				10	17	17	21
0014910	Disposable SpO2 Sensors - Paediatric.				4	9	23	11
0014911	Disposable SpO2 Sensors - Infant.				9	6	26	40
0014912	Disposable SpO2 Sensors - Neonatal.				106	219	19	140
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
0014925	Disposable SpO2 Sensors - Adult.				1	2	3	
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.							
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.							
0014953	Disposable SpO2 Sensors - Adult.							
0014954	Disposable SpO2 Sensors - Paediatric.							

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
0014957	Disposable SpO2 Sensors - Adult.					5	3	8
0014958	Disposable SpO2 Sensors - Paediatric.					10	10	10
0014959	Disposable SpO2 Sensors - Infant.					16	7	7
0014960	Disposable SpO2 Sensors - Neonatal.				1	1		3
0014961	Disposable SpO2 Sensors - Adult.							
0014962	Disposable SpO2 Sensors - Paediatric.							
0014963	Disposable SpO2 Sensors - Infant.							
0014964	Disposable SpO2 Sensors - Neonatal.							5
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.							
0014993	Disposable SpO2 Sensors - Adult.							2
0014994	Disposable SpO2 Sensors - Paediatric.					1	3	2
0014995	Disposable SpO2 Sensors - Infant.					1	1	2
0014996	Disposable SpO2 Sensors - Neonatal.					2	6	17

Comments on Sales Information:

No Comments on Sales

New Countries

Country	2005	2006	2007	2008	2009	2010	2011
B Belgium							[X]
CH Chile					[X]		
CZ Czech Republic				[X]	[X]	[X]	[X]
ES Estonia							[X]
FI Finland						[X]	[X]
G Germany				[X]		[X]	
GR Greece					[X]	[X]	[X]
IN India				[X]	[X]		
IRE Ireland				[X]	[X]	[X]	[X]
LEB Lebanon				[X]	[X]		
NG Nigera						[X]	
NO Norway					[X]	[X]	
P Poland					[X]		
PO Portugal				[X]	[X]	[X]	[X]
SAU Saudi Arabia				[X]	[X]		[X]
SP Spain				[X]	[X]	[X]	[X]
SW Sweden							[X]
UAE U.A.E.					[X]	[X]	[X]
UK United Kingdom				[X]	[X]	[X]	[X]

Comments on Sales to Countries:

B Belgium, ES Estonia, only new countries sold to

Comments on Risks with Sales to Countries:

No risks identified with new countries

Returns Information

Stock Reference	Fault	2005	2006	2007	2008	2009	2010	2011
0014909	No Fault Return to Stock							
0014910	No Fault Return to Stock							
0014911	No Fault Return to Stock							

Comments on Returns:

Zero faulty returns.

Comments on Risks with Returns and Potential Re-work:

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:

No risks

Documentation updates / Changes

Comments on Document Changes:

OBL file was brought upto date, and DOC files converted into PDF files

Comments on Risks with Document Changes:

no risks with new documentation

Review of Issues

Number of Issues reviewed: 32

Comments on Issues:

No Comments on issues

Comments on Risks with Issues:

No risks identified from the Issues

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 :