



16/Jan/2014

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 16 / 01 / 14

Stock References Reviewed

Stock Reference	Description
0014601	SpO2 Finger Sensor - Adult.
0014602	SpO2 Finger Sensor - Adult.
0014603	SpO2 Finger Sensor - Adult.
0014604	SpO2 Finger Sensor - Adult.
0014605	SpO2 Finger Sensor - Adult.
0014606	SpO2 Finger Sensor - Adult.
0014607	SpO2 Finger Sensor - Adult.
0014608	SpO2 Finger Sensor - Adult.
0014609	SpO2 Finger Sensor - Adult.
0014610	SpO2 Finger Sensor - Adult.
0014611	SpO2 Finger Sensor - Adult.
0014612	SpO2 Finger Sensor - Adult.
0014613	SpO2 Finger Sensor - Adult.
0014614	SpO2 Finger Sensor - Adult.
0014615	SpO2 Finger Sensor - Adult.
0014617	SpO2 Finger Sensor - Adult.
0014618	SpO2 Finger Sensor - Adult.
0014619	SpO2 Finger Sensor - Adult.
0014620	SpO2 Finger Sensor - Adult.
0014621	SpO2 Finger Sensor - Adult.
0014623	SpO2 Finger Sensor - Adult.
0014625	SpO2 Finger Sensor - Adult.
0014649	SpO2 Finger Sensor - Adult.
0014650	SpO2 Finger Sensor - Adult.
0014701	SpO2 Silicone Finger Sensor - Adult.
0014702	SpO2 Silicone Finger Sensor - Adult.
0014703	SpO2 Silicone Finger Sensor - Adult.
0014704	SpO2 Silicone Finger Sensor - Adult.
0014705	SpO2 Silicone Finger Sensor - Adult.
0014706	SpO2 Silicone Finger Sensor - Adult.
0014707	SpO2 Silicone Finger Sensor - Adult.
0014708	SpO2 Silicone Finger Sensor - Adult.
0014709	SpO2 Silicone Finger Sensor - Adult.
0014710	SpO2 Silicone Finger Sensor - Adult.
0014711	SpO2 Silicone Finger Sensor - Adult.
0014712	SpO2 Silicone Finger Sensor - Adult.
0014713	SpO2 Silicone Finger Sensor - Adult.
0014714	SpO2 Silicone Finger Sensor - Adult.
0014715	SpO2 Silicone Finger Sensor - Adult.
0014717	SpO2 Silicone Finger Sensor - Adult.
0014718	SpO2 Silicone Finger Sensor - Adult.
0014719	SpO2 Silicone Finger Sensor - Adult.
0014720	SpO2 Silicone Finger Sensor - Adult.
0014721	SpO2 Silicone Finger Sensor - Adult.
0014722	SpO2 Silicone Finger Sensor - Adult.

Stock Reference	Description
0014723	SpO2 Silicone Finger Sensor - Adult.
0014724	SpO2 Silicone Finger Sensor - Adult.
0014725	SpO2 Silicone Finger Sensor - Adult.
0014740	SpO2 Silicone Finger Sensor - Adult.
0014750	SpO2 Silicone Finger Sensor - Adult.
0014751	SpO2 Silicone Finger Sensor - Paediatric
0014755	SpO2 Silicone Finger Sensor - Adult.
0014756	SpO2 Silicone Finger Sensor - Paediatric
0014761	SpO2 Silicone Finger Sensor - Paediatric
0014762	SpO2 Silicone Finger Sensor - Paediatric
0014763	SpO2 Silicone Finger Sensor - Paediatric
0014764	SpO2 Silicone Finger Sensor - Paediatric
0014765	SpO2 Silicone Finger Sensor - Paediatric
0014766	SpO2 Silicone Finger Sensor - Paediatric
0014767	SpO2 Silicone Finger Sensor - Paediatric
0014768	SpO2 Silicone Finger Sensor - Paediatric
0014769	SpO2 Silicone Finger Sensor - Paediatric
0014770	SpO2 Silicone Finger Sensor - Paediatric
0014771	SpO2 Silicone Finger Sensor - Paediatric
0014772	SpO2 Silicone Finger Sensor - Paediatric
0014773	SpO2 Silicone Finger Sensor - Paediatric
0014774	SpO2 Silicone Finger Sensor - Paediatric
0014775	SpO2 Silicone Finger Sensor - Paediatric
0014777	SpO2 Silicone Finger Sensor - Paediatric
0014778	SpO2 Silicone Finger Sensor - Paediatric
0014779	SpO2 Silicone Finger Sensor - Paediatric
0014780	SpO2 Silicone Finger Sensor - Paediatric
0014781	SpO2 Silicone Finger Sensor - Paediatric
0014782	SpO2 Silicone Finger Sensor - Paediatric
0014785	SpO2 Silicone Finger Sensor - Paediatric
0014790	SpO2 Silicone Finger Sensor - Paediatric
0014801	Pulse Oximetry Ear Sensor
0014802	Pulse Oximetry Ear Sensor
0014803	Pulse Oximetry Ear Sensor
0014804	Pulse Oximetry Ear Sensor
0014805	Pulse Oximetry Ear Sensor
0014806	Pulse Oximetry Ear Sensor
0014807	Pulse Oximetry Ear Sensor
0014808	Pulse Oximetry Ear Sensor
0014816	Pulse Oximetry Ear Sensor
0014820	Pulse Oximetry Wrap Sensor
0014821	Pulse Oximetry Wrap Sensor
0014822	Pulse Oximetry Wrap Sensor
0014823	Pulse Oximetry Wrap Sensor
0014824	Pulse Oximetry Wrap Sensor
0014825	Pulse Oximetry Ear Sensor
0014826	Pulse Oximetry Wrap Sensor
0014827	Pulse Oximetry Wrap Sensor
0014828	Pulse Oximetry Wrap Sensor

Stock Reference	Description
0014829	Pulse Oximetry Wrap Sensor
0014830	Pulse Oximetry Wrap Sensor
0014831	Pulse Oximetry Wrap Sensor
0014832	Pulse Oximetry Wrap Sensor
0014833	Pulse Oximetry Wrap Sensor
0014834	Pulse Oximetry Wrap Sensor
0014835	Pulse Oximetry Wrap Sensor
0014836	Pulse Oximetry Wrap Sensor
0014837	Pulse Oximerty Wrap Sensor
0014838	Pulse Oximetry Wrap Sensor
0014840	Pulse Oximetry Wrap Sensor
0014841	Pulse Oximetry Wrap Sensor
0014842	Pulse Oximetry Wrap Sensor
0014843	Pulse Oximetry Wrap Sensor
0014844	Pulse Oximetry Wrap Sensor
0014845	Pulse Oximetry Multi-Site Y Sensor
0014848	Pulse Oximetry Wrap Sensor
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.

Stock Reference	Description
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.
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.

Stock Reference	Description
0014996	Disposable SpO2 Sensors - Neonatal.
0019001	Nellcor DEC-4 compatible SpO2 extension
0019002	Nellcor DEC-8 compatible SpO2 extension

Comments on Stock references review:

All references correct

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0014740	SpO2 Silicone Finger Sensor - Adult.	00009299	Bluepoint Medical	A
0014790	SpO2 Silicone Finger Sensor - Paediatric	00009299	Bluepoint Medical	A
0014901	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	A
0014902	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	A
0014903	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	A
0014904	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	A
0014905	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	A
0014906	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	A
0014909	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	A
0014910	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	A
0014911	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	A
0014912	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	A
0014925	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	A
0014926	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	A
0014927	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	A
0014928	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	A
0014957	Disposable SpO2 Sensors - Adult.	00009299	Bluepoint Medical	A
0014958	Disposable SpO2 Sensors - Paediatric.	00009299	Bluepoint Medical	A
0014959	Disposable SpO2 Sensors - Infant.	00009299	Bluepoint Medical	A
0014960	Disposable SpO2 Sensors - Neonatal.	00009299	Bluepoint Medical	A
0014601	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014602	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014603	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014604	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014605	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014606	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014607	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014608	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014609	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014611	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014612	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014617	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014618	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014625	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014650	SpO2 Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014701	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014702	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014703	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014704	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014705	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014706	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014707	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014708	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014709	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014710	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014713	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0014714	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014715	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014721	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014725	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014750	SpO2 Silicone Finger Sensor - Adult.	00009300	Bluepoint Medical	A
0014751	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014761	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014762	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014763	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014764	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014766	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014769	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014770	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014771	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014774	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014775	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014778	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014785	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014790	SpO2 Silicone Finger Sensor - Paediatric	00009300	Bluepoint Medical	A
0014801	Pulse Oximetry Ear Sensor	00009300	Bluepoint Medical	A
0014802	Pulse Oximetry Ear Sensor	00009300	Bluepoint Medical	A
0014804	Pulse Oximetry Ear Sensor	00009300	Bluepoint Medical	A
0014805	Pulse Oximetry Ear Sensor	00009300	Bluepoint Medical	A
0014807	Pulse Oximetry Ear Sensor	00009300	Bluepoint Medical	A
0014816	Pulse Oximetry Ear Sensor	00009300	Bluepoint Medical	A
0014820	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014822	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014823	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014824	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014825	Pulse Oximetry Ear Sensor	00009300	Bluepoint Medical	A
0014827	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014828	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014829	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014830	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014835	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
0014848	Pulse Oximetry Wrap Sensor	00009300	Bluepoint Medical	A
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
0014921	Disposable SpO2 Sensors - Adult.	00009300	Bluepoint Medical	A

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0014922	Disposable SpO2 Sensors - Paediatric.	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
0014960	Disposable SpO2 Sensors - Neonatal.	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
0019001	Nellcor DEC-4 compatible SpO2 extension	00009300	Bluepoint Medical	A
0019002	Nellcor DEC-8 compatible SpO2 extension	00009300	Bluepoint Medical	A
0031238	Connector kit Philips/HP 8 pins.	00012399	Unimed	B
0031256	Connector kit Nihon Kohden.	00012399	Unimed	B

Comments on Suppliers:

Unimed Listed, however they are for the older 800 series probes.
needs to be removed from this supplier list

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0014601	SpO2 Finger Sensor - Adult.	32	13	11	59	6	20	
0014602	SpO2 Finger Sensor - Adult.	41	65	75	5	0	2	
0014603	SpO2 Finger Sensor - Adult.				1			
0014604	SpO2 Finger Sensor - Adult.	1	5	4			11	
0014605	SpO2 Finger Sensor - Adult.			1	4	5	4	
0014606	SpO2 Finger Sensor - Adult.		7	38	73	54	50	2
0014607	SpO2 Finger Sensor - Adult.		16	58	54	21	9	
0014608	SpO2 Finger Sensor - Adult.			13	18	22	16	
0014609	SpO2 Finger Sensor - Adult.			6	18	5	5	1
0014610	SpO2 Finger Sensor - Adult.				8	8	7	
0014611	SpO2 Finger Sensor - Adult.			1	7	3	7	
0014612	SpO2 Finger Sensor - Adult.			9	28	14	13	1
0014613	SpO2 Finger Sensor - Adult.					3		
0014614	SpO2 Finger Sensor - Adult.							
0014615	SpO2 Finger Sensor - Adult.							
0014617	SpO2 Finger Sensor - Adult.						3	
0014618	SpO2 Finger Sensor - Adult.						5	
0014619	SpO2 Finger Sensor - Adult.							
0014620	SpO2 Finger Sensor - Adult.							
0014621	SpO2 Finger Sensor - Adult.				5			
0014623	SpO2 Finger Sensor - Adult.						8	
0014625	SpO2 Finger Sensor - Adult.				37	28	32	
0014649	SpO2 Finger Sensor - Adult.						45	
0014650	SpO2 Finger Sensor - Adult.	8	2	4	135	228	215	
0014701	SpO2 Silicone Finger Sensor - Adult.	6	23	25	32	17	2	
0014702	SpO2 Silicone Finger Sensor - Adult.	2	13	5	12	1	1	
0014703	SpO2 Silicone Finger Sensor - Adult.	4	7	12	6	18		
0014704	SpO2 Silicone Finger Sensor - Adult.		55	100	100	77	76	
0014705	SpO2 Silicone Finger Sensor - Adult.					2		
0014706	SpO2 Silicone Finger Sensor - Adult.			3	29	13	4	
0014707	SpO2 Silicone Finger Sensor - Adult.						15	
0014708	SpO2 Silicone Finger Sensor - Adult.					1		
0014709	SpO2 Silicone Finger Sensor - Adult.				2			
0014710	SpO2 Silicone Finger Sensor - Adult.					2		
0014711	SpO2 Silicone Finger Sensor - Adult.							
0014712	SpO2 Silicone Finger Sensor - Adult.						10	
0014713	SpO2 Silicone Finger Sensor - Adult.							
0014714	SpO2 Silicone Finger Sensor - Adult.							
0014715	SpO2 Silicone Finger Sensor - Adult.		62	62	46	12	37	
0014717	SpO2 Silicone Finger Sensor - Adult.							
0014718	SpO2 Silicone Finger Sensor - Adult.							
0014719	SpO2 Silicone Finger Sensor - Adult.							
0014720	SpO2 Silicone Finger Sensor - Adult.							
0014721	SpO2 Silicone Finger Sensor - Adult.							
0014722	SpO2 Silicone Finger Sensor - Adult.							
0014723	SpO2 Silicone Finger Sensor - Adult.		6	22	25	30	23	

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0014724	SpO2 Silicone Finger Sensor - Adult.			2		11	8	
0014725	SpO2 Silicone Finger Sensor - Adult.			15	55	3	8	
0014740	SpO2 Silicone Finger Sensor - Adult.	500	1500					
0014750	SpO2 Silicone Finger Sensor - Adult.	9	33	265	304	409	684	12
0014751	SpO2 Silicone Finger Sensor - Paediatric	22	65	72	60	47	51	5
0014755	SpO2 Silicone Finger Sensor - Adult.							
0014756	SpO2 Silicone Finger Sensor - Paediatric							
0014761	SpO2 Silicone Finger Sensor - Paediatric		7	11	10		22	
0014762	SpO2 Silicone Finger Sensor - Paediatric		17	19	59	9	25	
0014763	SpO2 Silicone Finger Sensor - Paediatric					1		
0014764	SpO2 Silicone Finger Sensor - Paediatric				5		3	
0014765	SpO2 Silicone Finger Sensor - Paediatric							
0014766	SpO2 Silicone Finger Sensor - Paediatric				1	5	2	
0014767	SpO2 Silicone Finger Sensor - Paediatric							
0014768	SpO2 Silicone Finger Sensor - Paediatric			1				
0014769	SpO2 Silicone Finger Sensor - Paediatric				1			
0014770	SpO2 Silicone Finger Sensor - Paediatric					1		
0014771	SpO2 Silicone Finger Sensor - Paediatric				2			
0014772	SpO2 Silicone Finger Sensor - Paediatric							
0014773	SpO2 Silicone Finger Sensor - Paediatric							
0014774	SpO2 Silicone Finger Sensor - Paediatric						3	
0014775	SpO2 Silicone Finger Sensor - Paediatric		8	3			5	
0014777	SpO2 Silicone Finger Sensor - Paediatric							
0014778	SpO2 Silicone Finger Sensor - Paediatric			2				
0014779	SpO2 Silicone Finger Sensor - Paediatric							
0014780	SpO2 Silicone Finger Sensor - Paediatric							
0014781	SpO2 Silicone Finger Sensor - Paediatric							
0014782	SpO2 Silicone Finger Sensor - Paediatric							
0014785	SpO2 Silicone Finger Sensor - Paediatric				23	7	1	
0014790	SpO2 Silicone Finger Sensor - Paediatric		198					
0014801	Pulse Oximetry Ear Sensor			2	5	12	8	
0014802	Pulse Oximetry Ear Sensor			8	11	9	28	
0014803	Pulse Oximetry Ear Sensor							
0014804	Pulse Oximetry Ear Sensor		2	10	12	20	25	
0014805	Pulse Oximetry Ear Sensor			1				
0014806	Pulse Oximetry Ear Sensor							
0014807	Pulse Oximetry Ear Sensor					6	3	
0014808	Pulse Oximetry Ear Sensor							
0014816	Pulse Oximetry Ear Sensor					18	17	
0014820	Pulse Oximetry Wrap Sensor							
0014821	Pulse Oximetry Wrap Sensor		3			4	15	
0014822	Pulse Oximetry Wrap Sensor				3	5		
0014823	Pulse Oximetry Wrap Sensor					4		
0014824	Pulse Oximetry Wrap Sensor				7	7	6	
0014825	Pulse Oximetry Ear Sensor			15	39	34	70	2
0014826	Pulse Oximetry Wrap Sensor							
0014827	Pulse Oximetry Wrap Sensor							
0014828	Pulse Oximetry Wrap Sensor		4	5	2	3		
0014829	Pulse Oximetry Wrap Sensor			1			1	

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0014830	Pulse Oximetry Wrap Sensor				1			
0014831	Pulse Oximetry Wrap Sensor							
0014832	Pulse Oximetry Wrap Sensor							
0014833	Pulse Oximetry Wrap Sensor							
0014834	Pulse Oximetry Wrap Sensor							
0014835	Pulse Oximetry Wrap Sensor		27	60	35	36	60	
0014836	Pulse Oximetry Wrap Sensor							
0014837	Pulse Oximerty Wrap Sensor							
0014838	Pulse Oximetry Wrap Sensor							
0014840	Pulse Oximetry Wrap Sensor							
0014841	Pulse Oximetry Wrap Sensor							
0014842	Pulse Oximetry Wrap Sensor							
0014843	Pulse Oximetry Wrap Sensor							
0014844	Pulse Oximetry Wrap Sensor							
0014845	Pulse Oximetry Multi-Site Y Sensor							
0014848	Pulse Oximetry Wrap Sensor					22		
0014895	Pulse Oximetry Extension Cable 1.2 m	8	7	8	11	26	35	
0014896	Pulse Oximetry Extension Cable 2.4 m		1	4	4	3	3	
0014901	Disposable SpO2 Sensors - Adult.	3	11	65	51	22	15	
0014902	Disposable SpO2 Sensors - Paediatric.	3	3	13	10	15	15	
0014903	Disposable SpO2 Sensors - Infant.	3	6	6	8			
0014904	Disposable SpO2 Sensors - Neonatal.	54	77	68	43	18	15	
0014905	Disposable SpO2 Sensors - Adult.	36	19	20	50	49	42	6
0014906	Disposable SpO2 Sensors - Paediatric.	113	182	178	22	49	5	
0014909	Disposable SpO2 Sensors - Adult.	10	17	17	21		318	40
0014910	Disposable SpO2 Sensors - Paediatric.	4	9	23	12	5	13	
0014911	Disposable SpO2 Sensors - Infant.	9	6	26	40	30	232	
0014912	Disposable SpO2 Sensors - Neonatal.	106	219	19	146	206	66	
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	3	
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.							

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0014938	Disposable SpO2 Sensors - Paediatric.							
0014939	Disposable SpO2 Sensors - Infant.							
0014940	Disposable SpO2 Sensors - Neonatal.					5		
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.							
0014957	Disposable SpO2 Sensors - Adult.		5	3	8	4	12	
0014958	Disposable SpO2 Sensors - Paediatric.		10	10	10	18	24	
0014959	Disposable SpO2 Sensors - Infant.		16	7	7	28	45	
0014960	Disposable SpO2 Sensors - Neonatal.	1	1		5	24	25	
0014961	Disposable SpO2 Sensors - Adult.							
0014962	Disposable SpO2 Sensors - Paediatric.							
0014963	Disposable SpO2 Sensors - Infant.							
0014964	Disposable SpO2 Sensors - Neonatal.				5	3	2	
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		7	2
0014990	Disposable SpO2 Sensors - Paediatric.				1		1	
0014993	Disposable SpO2 Sensors - Adult.				2			
0014994	Disposable SpO2 Sensors - Paediatric.		1	3	3		10	
0014995	Disposable SpO2 Sensors - Infant.		1	1	4	5	4	
0014996	Disposable SpO2 Sensors - Neonatal.		2	6	17	28	22	

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0019001	Nellcor DEC-4 compatible SpO2 extension			9	28	18	6	
0019002	Nellcor DEC-8 compatible SpO2 extension				1	1	2	

Comments on Sales Information:

New Countries

Country	2008	2009	2010	2011	2012	2013	2014
AU Austria			[X]	[X]	[X]	[X]	
B Belgium		[X]	[X]	[X]	[X]	[X]	[X]
BA State of Bahrain						[X]	
C China						[X]	
CAN Canada		[X]				[X]	
CH Chile		[X]			[X]		
CI Canaria Islands				[X]			
CRO Croatia				[X]			
CY Cyprus				[X]		[X]	
CZ Czech Republic	[X]	[X]	[X]	[X]	[X]	[X]	
DE Denmark	[X]	[X]	[X]	[X]	[X]	[X]	
EG Egypt				[X]			
ES Estonia				[X]		[X]	
F France			[X]	[X]	[X]	[X]	[X]
FI Finland			[X]	[X]	[X]	[X]	
G Germany	[X]	[X]	[X]	[X]	[X]	[X]	
GR Greece	[X]	[X]	[X]	[X]	[X]	[X]	
HK Hong Kong				[X]	[X]	[X]	
I Iran		[X]	[X]	[X]	[X]	[X]	
IN India	[X]	[X]	[X]	[X]	[X]		
IND Indonesia						[X]	
IQ IRAQ						[X]	[X]
IRE Ireland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
IS Israel			[X]		[X]		
JO Jordan		[X]			[X]		
KE Kenya		[X]	[X]		[X]		
KU Kuwait				[X]			
LEB Lebanon	[X]	[X]	[X]		[X]		
MA Malaysia	[X]	[X]	[X]	[X]	[X]	[X]	
MAU Mauritius						[X]	
NE Netherlands		[X]	[X]		[X]		
NG Nigera			[X]				
NO Norway		[X]	[X]	[X]	[X]	[X]	
NZ New Zealand						[X]	
OM Oman		[X]	[X]		[X]	[X]	
P Poland		[X]	[X]	[X]	[X]	[X]	
PO Portugal	[X]	[X]	[X]	[X]	[X]	[X]	[X]
RO Romania			[X]	[X]	[X]	[X]	
RU Russia						[X]	
SA South Africa				[X]	[X]		
SAU Saudi Arabia	[X]	[X]	[X]	[X]	[X]	[X]	[X]
SI Singapore					[X]		
SL Slovenia						[X]	
SP Spain	[X]	[X]	[X]	[X]	[X]	[X]	
SRI Sri Lanka						[X]	
SW Sweden			[X]	[X]	[X]	[X]	

Country	2008	2009	2010	2011	2012	2013	2014
SWI Switzerland		[X]		[X]		[X]	
SY Syria			[X]	[X]			
T Turkey	[X]	[X]	[X]	[X]	[X]	[X]	
TH Thailand	[X]	[X]		[X]	[X]	[X]	
UAE U A E					[X]	[X]	
UAE U.A.E.		[X]	[X]	[X]			
UG UGANDA						[X]	
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
VI Vietnam				[X]	[X]	[X]	

Comments on Sales to Countries:

Comments on Risks with Sales to Countries:

Returns Information

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0014601	Faulty probe				1			
0014601	Intermittent				1			
0014601	Low SpO2 readings				1			
0014601	Unchecked - Returned to Stock							
0014602	Unchecked - Returned to Stock							
0014605	Unchecked - Returned to Stock							
0014606	Connector damaged				1			
0014606	Damaged finger clip				1			
0014606	Faulty Electronics				1			
0014606	Faulty probe				2			
0014606	Intermittent				1	1		
0014607	Faulty probe				1	2		
0014607	Unchecked - Returned to Stock							
0014608	Faulty probe					2		
0014608	Intermittant			1	1			
0014608	Intermittent			1		2		
0014608	Investigate				1			
0014608	No fault found				1	1		
0014609	Unchecked - Returned to Stock							
0014610	Unchecked - Returned to Stock							
0014612	Unchecked - Returned to Stock							
0014625	Intermittent				1	1		
0014649	Faulty probe						3	
0014649	Sensor Fault						3	
0014650	Chip shorts to emitter						1	
0014650	Chip shorts to photodiode						4	
0014650	Emitter intermittent at the connector						2	
0014650	Faulty probe				3	19	13	
0014650	Intermittent				2			
0014650	No Fault Found				1	2		
0014650	Photodiode intermittent at the connector						2	
0014650	Sensor Fault					4	7	
0014701	Intermittent				1	1		
0014701	No Fault Found		1			1		
0014701	Red emitter faulty.					1		
0014703	Faulty Electronics			1				
0014703	Faulty probe				1	1		
0014703	Silicone moulding split		1	1				
0014703	Unchecked - Returned to Stock							
0014704	Break at the connector					4		
0014704	Damaged finger clip		1					
0014704	Faulty Electronics				1			
0014704	Faulty probe					7		
0014704	Intermittant			1				
0014704	Intermittent				1	2		
0014704	No Fault Found				1			

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0014704	No Fault Return to Stock							
0014704	Red emitter faulty.					1		
0014704	Unit dead					1		
0014706	Connector damaged				2			
0014706	Not working on monitor				1			
0014715	Damaged finger clip			3				
0014715	Faulty Electronics			1				
0014715	Intermittent			4	2			
0014715	Not working on monitor			2				
0014750	Connector damaged			1		1		
0014750	Damaged finger clip				1			
0014750	Declined quote					2		
0014750	Faulty Electronics			1				
0014750	Faulty probe				1	4	8	
0014750	Intermittant						4	
0014750	Intermittent		2				1	
0014750	No fault found	1		1	1	3	3	
0014750	No Fault Return to Stock							
0014750	Not working on monitor			1				
0014750	Photodiode intermittent at the connector						2	
0014750	Sensor Fault					1	1	
0014750	Unable to repair			2				
0014750	Unchecked - Returned to Stock							
0014751	Faulty probe					1		
0014751	No Fault Found			1				
0014804	Faulty electronics				1			
0014804	Unchecked - Returned to Stock							
0014825	Faulty electronics						1	
0014825	No Fault Found				2	1	3	
0014825	Sensor fault						1	
0014825	Unable to repair					1		
0014835	Intermittent			1			1	
0014835	No Fault Found						1	
0014835	Unchecked - Returned to Stock							
0014905	Unchecked - Returned to Stock							
0014909	No Fault Return to Stock							
0014910	No Fault Return to Stock							
0014911	No Fault Return to Stock							
0014911	Unchecked - Returned to Stock							
0014912	Unchecked - Returned to Stock							
0014924	Unchecked - Returned to Stock							
0014960	Unchecked - Returned to Stock							
0014995	Unchecked - Returned to Stock							

Comments on Returns:

Still selling accross the range of products

Comments on Risks with Returns and Potential Re-work:

no risks idientified in the returns service

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes to documentation

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:

no changes to the user instructions

Comments on Risks User Instructions:

n/a

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
13098	Pulse Oximetry Sensors 4000 Series Labels	21/10/13
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:

Label PDF updated, however the actual label have not been changed

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Comments on Document Changes:

some of the documentation has been upgraded,
but no significant changes

Comments on Risks with Document Changes:

n/a

Review of Issues

Number of Issues reviewed: 54

Issue ID	Subject
47445	Proforma for ex-demo VM-2160
46983	Returned Items SOR588
46955	Returned Items SOR589
46853	Returned Items SOR559
46677	Returned Items SOR581
46550	Returned Items SOR572
45703	Returned Items SOR482
45152	Returned Items SOR567
44975	Returned Items SOR533
44513	Theramed - SOR581
43291	Returned Items SOR557
43290	Returned Items SOR551
43261	Returned Items SOR511
42989	Request Scanning Item to Sale or return
42869	Returned Items SOR546
42761	Returned Items SOR548
42669	Returned Items SOR544
42579	Request Scanning Item to Sale or return
41828	Returned Items SOR514
40595	Returned Items SOR537
43425	Capnograph Section
46673	Back Orders
40881	0014750 s/n: EAK02377 scanned to Arab Health need to check in bag
41501	Repair Approved SRS63710
45229	PETO/GHX Export - Requires sending
45167	Group Peto Group - Export - <p>
44817	Group Peto Group - Export
44493	Stock Group - GHX/Peto - duplicate part
40459	tell me about
42582	Certificate of Origins - Capnograph and MAX-250A Sensor
42581	Certificate of Origins - Capnograph and MAX-250A Sensor
42580	Certificate of Origins - Capnograph and MAX-250A Sensor
46674	Production 0014723
45590	Yorkshire Ambulance consignment stock levels
45589	Yorkshire Ambulance consignment stock levels
45588	Yorkshire Ambulance consignment stock levels
45587	Yorkshire Ambulance consignment stock levels
45586	Yorkshire Ambulance consignment stock levels
46313	New box label needed
45969	Need Box Label
45764	Label Description
40522	Stock to check
40463	do these exist?
40460	can you locate
44979	Viamed Version of Phototherapy Eye Masks/Capnograph accesories

Issue ID	Subject
37683	Update To Oximeter Sensor Price Lists
41420	SRS63697
44345	Attikouris - Transport Costs
44344	Tender Samples Required - Attikouris Enterprises Ltd. Cyprus
44343	Tender Samples Required - Attikouris Enterprises Ltd. Cyprus
43725	0014723 - Box Label - Oxylink
40341	Merivaara & Ata - 4000 Series - 0014650 Quality Issue
44432	0019001 & 0019002 Declaration of Conformity
44431	0019001 & 0019002 Declaration of Conformity

Comments on Issues:

stock processing Issues , lots of sale or return Items,

Comments on Risks with Issues:

No risks identified 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 :

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 :