



24/Oct/2011

Post market Surveillance and Risk Assessment Re-evaluation

Pulse Oximeter Probes
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
0018520	SpO2 finger sensor P852RA.
0018522	SpO2 finger sensor P85AYA.
0018530	SpO2 finger sensor P853RA.
0018540	SpO2 finger sensor P854RA.
0018550	SpO2 finger sensor P855RA.
0018560	SpO2 finger sensor P856RA.
0018562	SpO2 multi-site `Y` sensor P856YA.
0018567	Cable assembly - finger adult pack of 5.
0018570	SpO2 finger sensor P857RA.
0018572	SpO2 multi-site `Y` sensor P857YA.
0018577	Cable assembly - finger adult pack of 5.
0018580	SpO2 finger sensor P858RA.
0018582	SpO2 multi-site `Y` sensor P858YA.
0018587	Cable assembly - finger adult pack of 5.
0018590	SpO2 finger sensor P859RA.
0018592	SpO2 multi-site `Y` sensor P859YA.
0018600	SpO2 finger sensor P860RA.
0018602	SpO2 multi-site `Y` sensor P860YA.
0018607	Cable assembly - finger adult pack of 5.
0018610	SpO2 finger sensor P861RA.
0018612	SpO2 multi-site `Y` sensor P861YA.
0018617	Cable assembly - finger adult pack of 5.
0018620	SpO2 finger sensor P862RA.
0018622	SpO2 multi-site `Y` sensor P862YA.
0018627	Cable assembly - finger adult pack of 5.
0018630	SpO2 finger sensor P863RA.
0018632	SpO2 multi-site `Y` sensor P863YA.
0018640	SpO2 finger sensor P864RA.
0018642	SpO2 multi-site `Y` sensor P864YA.
0018647	Cable assembly - finger adult pack of 5.
0018650	SpO2 finger sensor P865RA.
0018652	SpO2 multi-site `Y` sensor P865YA.
0018657	Cable assembly - finger adult pack of 5.
0018660	SpO2 finger sensor P866RA.
0018662	SpO2 multi-site `Y` sensor P866YA.
0018670	SpO2 finger sensor P867RA.
0018672	SpO2 multi-site `Y` sensor P867YA.
0018677	Cable assembly - finger adult pack of 5.
0018680	SpO2 finger sensor P868RA.
0018687	Cable assembly - finger adult pack of 5.
0018690	SpO2 finger sensor P869RA.
0018692	SpO2 multi-site `Y` sensor P869YA.
0018697	Cable assembly - finger adult pack of 5.
0018700	SpO2 finger sensor P870RA.
0018707	Cable assembly - finger adult pack of 5.

Stock Reference	Description
0018710	SpO2 finger sensor P871RA.
0018712	SpO2 multi-site `Y` sensor P871YA.
0018717	Cable assembly - finger adult pack of 5.
0018720	SpO2 finger sensor P872RA.
0018722	SpO2 multi-site `Y` sensor P872YA.
0018727	Cable assembly - finger adult pack of 5.
0018730	SpO2 finger sensor P873RA.
0018732	SpO2 multi-site `Y` sensor P873YA.
0018737	Cable assembly - finger adult pack of 5.
0018740	SpO2 finger sensor P874RA.
0018750	SpO2 finger sensor P875RA.
0018752	SpO2 multi-site `Y` sensor P875YA.
0018760	SpO2 finger sensor P876RA.
0018762	SpO2 multi-site `Y` sensor P876YA.
0018767	Cable assembly - finger adult pack of 5.
0018770	SpO2 finger sensor P877RA.
0018772	SpO2 multi-site `Y` sensor P877YA.
0018777	Cable assembly - finger adult pack of 5.
0018780	SpO2 finger sensor P878RA.
0018782	SpO2 multi-site `Y` sensor P878YA.
0018787	Cable assembly - finger adult pack of 5.
0018790	SpO2 finger sensor P879RA.
0018797	Cable assembly - finger adult pack of 5.
0018800	SpO2 finger sensor P880RA.
0018810	SpO2 finger sensor P881RA.
0018820	SpO2 finger sensor P882RA.
0018830	SpO2 finger sensor P883RA.
0018850	SpO2 finger sensor P885RA.
0018860	SpO2 finger sensor P886RA.
0018862	SpO2 multi-site `Y` sensor P886YA.
0018867	Cable assembly - finger adult pack of 5.
0018870	SpO2 finger sensor P887RA.
0018872	SpO2 multi-site `Y` sensor P887YA.
0018877	Cable assembly - finger adult pack of 5.
0018880	SpO2 finger sensor P888RA.
0018882	SpO2 multi-site `Y` sensor P888YA.
0018887	Cable assembly - finger adult pack of 5.
0018890	SpO2 finger sensor P889RA.
0018892	SpO2 multi-site `Y` sensor P889YA.
0018897	Cable assembly - finger adult pack of 5.
0018900	SpO2 finger sensor P890RA.
0018902	SpO2 multi-site `Y` sensor P890YA.
0018910	SpO2 finger sensor P891RA.
0018912	SpO2 multi-site `Y` sensor P891YA.
0018917	Cable assembly - finger adult pack of 5.
0018920	SpO2 finger sensor P892RA.
0018922	SpO2 multi-site `Y` sensor P892YA.
0018930	SpO2 finger sensor P893RA.
0018940	SpO2 finger sensor P894RA.

Stock Reference	Description
0018950	SpO2 finger sensor P895RA.
0018960	SpO2 finger sensor P896RA.
0018962	SpO2 multi-site `Y` sensor P896RA.
0018970	SpO2 finger sensor P897RA.
0018990	CONSIGNED STOCK: SpO2 finger sensor.

Comments on Stock references review:

All parts now added

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0018610	SpO2 finger sensor P861RA.	00007820	Medical Cables Inc.	B
0018640	SpO2 finger sensor P864RA.	00007820	Medical Cables Inc.	B
0018670	SpO2 finger sensor P867RA.	00007820	Medical Cables Inc.	B
0018720	SpO2 finger sensor P872RA.	00007820	Medical Cables Inc.	B
0018760	SpO2 finger sensor P876RA.	00007820	Medical Cables Inc.	B
0030650	Lemo 5 pole cable plug connector.	00009825	Lemo UK	B
0030651	Lemo 7 pole cable plug connector.	00009825	Lemo UK	B
0030654	Lemo connector strain relief boot white	00009825	Lemo UK	B
0010759	Sub miniature D connector plug kit	00010356	Advantage Medical	B
0030701	Nihon Kohden connector.	00010356	Advantage Medical	B
0030759	Sub miniature D connector plug kit	00010356	Advantage Medical	B
0030598	Box - SpO2 probes blue.	00010440	Gard Plastics	B
0009564	SpO2 extension cable P956E4.	00010911	Spacelabs Healthcare Pte. Ltd.	B
0018640	SpO2 finger sensor P864RA.	00010911	Spacelabs Healthcare Pte. Ltd.	B
0018670	SpO2 finger sensor P867RA.	00010911	Spacelabs Healthcare Pte. Ltd.	B
0018672	SpO2 multi-site `Y` sensor P867YA.	00010911	Spacelabs Healthcare Pte. Ltd.	B
0038587	Cable assembly for P858RA.	00010911	Spacelabs Healthcare Pte. Ltd.	B
0038897	Cable assembly for P889RA.	00010911	Spacelabs Healthcare Pte. Ltd.	B
0010602	12 pin cable plug kit grey.	00011701	CCS Electronics	B
0010706	Socket Plug Connector Kit 10 way	00011858	Precision Interconnect GmbH	B
0010717	6 Pin Plug Palco.	00011931	AX Distribution	B
0031201	Sub miniature D connector plug kit	00012399	Unimed	B
0009564	SpO2 extension cable P956E4.	00012417	Cablemaster Technologies Ltd	B
0038587	Cable assembly for P858RA.	00012417	Cablemaster Technologies Ltd	B

Comments on Suppliers:

Medical cables / Spacelabs no longer suppliers

Sales Information

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
0018520	SpO2 finger sensor P852RA.		1	5		1		
0018522	SpO2 finger sensor P85AYA.							
0018530	SpO2 finger sensor P853RA.							
0018540	SpO2 finger sensor P854RA.	3				2		
0018550	SpO2 finger sensor P855RA.	10		3		5	10	
0018560	SpO2 finger sensor P856RA.	762	452	146	104	51	44	10
0018562	SpO2 multi-site `Y` sensor P856YA.	76		3				
0018567	Cable assembly - finger adult pack of 5.	32						
0018570	SpO2 finger sensor P857RA.	44	2	11	5	6	1	
0018572	SpO2 multi-site `Y` sensor P857YA.	22	1	3				
0018577	Cable assembly - finger adult pack of 5.							
0018580	SpO2 finger sensor P858RA.	122	56	103	8		1	
0018582	SpO2 multi-site `Y` sensor P858YA.	31	22	11	3			
0018587	Cable assembly - finger adult pack of 5.	4						
0018590	SpO2 finger sensor P859RA.	1						
0018592	SpO2 multi-site `Y` sensor P859YA.	1						
0018600	SpO2 finger sensor P860RA.	12	12					
0018602	SpO2 multi-site `Y` sensor P860YA.	12		1				
0018607	Cable assembly - finger adult pack of 5.							
0018610	SpO2 finger sensor P861RA.	82	28	57	18	7	3	
0018612	SpO2 multi-site `Y` sensor P861YA.	11	17	12	1			
0018617	Cable assembly - finger adult pack of 5.							
0018620	SpO2 finger sensor P862RA.	68	7	14	8	3	3	2
0018622	SpO2 multi-site `Y` sensor P862YA.							
0018627	Cable assembly - finger adult pack of 5.							
0018630	SpO2 finger sensor P863RA.	30	9	5	5	1		30
0018632	SpO2 multi-site `Y` sensor P863YA.							
0018640	SpO2 finger sensor P864RA.	268	210	114	182	96	167	32
0018642	SpO2 multi-site `Y` sensor P864YA.	5	3	0				
0018647	Cable assembly - finger adult pack of 5.							
0018650	SpO2 finger sensor P865RA.	34	57	44	14	10	1	9
0018652	SpO2 multi-site `Y` sensor P865YA.							
0018657	Cable assembly - finger adult pack of 5.							
0018660	SpO2 finger sensor P866RA.	1						2
0018662	SpO2 multi-site `Y` sensor P866YA.	1						
0018670	SpO2 finger sensor P867RA.	240	89	132	63	44	7	
0018672	SpO2 multi-site `Y` sensor P867YA.	95	21	14	2			
0018677	Cable assembly - finger adult pack of 5.							
0018680	SpO2 finger sensor P868RA.	11	16	16	21	34	17	4
0018687	Cable assembly - finger adult pack of 5.							
0018690	SpO2 finger sensor P869RA.	8	3	6	1		1	
0018692	SpO2 multi-site `Y` sensor P869YA.	19	1	6				
0018697	Cable assembly - finger adult pack of 5.							
0018700	SpO2 finger sensor P870RA.	44	56	76	57	28	40	10
0018707	Cable assembly - finger adult pack of 5.	2						
0018710	SpO2 finger sensor P871RA.	21	35	19	11	9	12	1

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
0018712	SpO2 multi-site `Y` sensor P871YA.		2					
0018717	Cable assembly - finger adult pack of 5.							
0018720	SpO2 finger sensor P872RA.	210	90	63	84	57	57	6
0018722	SpO2 multi-site `Y` sensor P872YA.							
0018727	Cable assembly - finger adult pack of 5.							
0018730	SpO2 finger sensor P873RA.	106	49	39	14	1	1	
0018732	SpO2 multi-site `Y` sensor P873YA.	14	8	6				
0018737	Cable assembly - finger adult pack of 5.	2						
0018740	SpO2 finger sensor P874RA.		7	2		1		2
0018750	SpO2 finger sensor P875RA.	2				1	2	
0018752	SpO2 multi-site `Y` sensor P875YA.	1	1					
0018760	SpO2 finger sensor P876RA.	59	10	50	3	2	3	
0018762	SpO2 multi-site `Y` sensor P876YA.	11	5	1				
0018767	Cable assembly - finger adult pack of 5.							
0018770	SpO2 finger sensor P877RA.		3	6				
0018772	SpO2 multi-site `Y` sensor P877YA.							
0018777	Cable assembly - finger adult pack of 5.							
0018780	SpO2 finger sensor P878RA.	18	2					
0018782	SpO2 multi-site `Y` sensor P878YA.	1						
0018787	Cable assembly - finger adult pack of 5.							
0018790	SpO2 finger sensor P879RA.	5	16	3	3	13		18
0018797	Cable assembly - finger adult pack of 5.							
0018800	SpO2 finger sensor P880RA.	0	2		1			
0018810	SpO2 finger sensor P881RA.			182	144	198	174	142
0018820	SpO2 finger sensor P882RA.			12	9	1		
0018830	SpO2 finger sensor P883RA.							7
0018850	SpO2 finger sensor P885RA.	1		4				
0018860	SpO2 finger sensor P886RA.	31	17					9
0018862	SpO2 multi-site `Y` sensor P886YA.	2	3	1				
0018867	Cable assembly - finger adult pack of 5.							
0018870	SpO2 finger sensor P887RA.	76	20	10	12	10		
0018872	SpO2 multi-site `Y` sensor P887YA.	10						
0018877	Cable assembly - finger adult pack of 5.							
0018880	SpO2 finger sensor P888RA.	82	60	30	20	3		
0018882	SpO2 multi-site `Y` sensor P888YA.							
0018887	Cable assembly - finger adult pack of 5.							
0018890	SpO2 finger sensor P889RA.		2					
0018892	SpO2 multi-site `Y` sensor P889YA.							
0018897	Cable assembly - finger adult pack of 5.							
0018900	SpO2 finger sensor P890RA.	1						
0018902	SpO2 multi-site `Y` sensor P890YA.							
0018910	SpO2 finger sensor P891RA.	16	4	11	-1		20	20
0018912	SpO2 multi-site `Y` sensor P891YA.							
0018917	Cable assembly - finger adult pack of 5.							
0018920	SpO2 finger sensor P892RA.	2	2	1	1		1	
0018922	SpO2 multi-site `Y` sensor P892YA.	5						
0018930	SpO2 finger sensor P893RA.							
0018940	SpO2 finger sensor P894RA.				2			
0018950	SpO2 finger sensor P895RA.	13	12					

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
0018960	SpO2 finger sensor P896RA.	6				1	1	1
0018962	SpO2 multi-site `Y` sensor P896RA.	0						
0018970	SpO2 finger sensor P897RA.							
0018990	CONSIGNED STOCK: SpO2 finger sensor.							

Comments on Sales Information:

New Countries

Country	2005	2006	2007	2008	2009	2010	2011
AU Austria							
AUS Australia							
B Belgium	[X]	[X]					
BA State of Bahrain							
CAN Canada							
CH Chile	[X]		[X]	[X]		[X]	[X]
CHA Channel Islands					[X]		
CZ Czech Republic	[X]						
DE Denmark							
EG Egypt	[X]						
EX Export sales	[X]						
F France	[X]	[X]	[X]	[X]	[X]		
G Germany	[X]	[X]	[X]	[X]	[X]		[X]
GR Greece	[X]	[X]	[X]				
HK Hong Kong		[X]					
HU Hungary							[X]
I Iran	[X]	[X]	[X]				
IN India							
IRE Ireland	[X]	[X]	[X]		[X]		
IS Israel							
IT Italy	[X]	[X]	[X]	[X]	[X]		
J Japan							
JO Jordan	[X]	[X]	[X]				
KE Kenya	[X]	[X]	[X]				
KU Kuwait							
LEB Lebanon							
MAU Mauritius		[X]	[X]				
NE Netherlands	[X]	[X]	[X]	[X]	[X]	[X]	
NO Norway							
NZ New Zealand							
P Poland							
PA Pakistan	[X]						
PO Portugal	[X]	[X]	[X]	[X]	[X]	[X]	[X]
Q Qatar					[X]		
SA South Africa	[X]	[X]	[X]				
SAU Saudi Arabia							[X]
SP Spain	[X]	[X]	[X]	[X]	[X]	[X]	
SRI Sri Lanka							
SY Syria							
T Turkey	[X]				[X]		
UAE U.A.E.					[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA U.S.A.							
VE Venezuela							

Comments on Sales to Countries:

HU Hungary,SAU Saudi Arabia only new countires 2011

Comments on Risks with Sales to Countries:

no new risk identifeid

Returns Information

Stock Reference	Fault	2005	2006	2007	2008	2009	2010	2011
0018560	Intermittant							
0018560	Repaired clip							
0018560	Replace clip, connector and cable				1			
0018560	Uneconomical to repair							
0018560	Uneconomical to repair, service exchange							
0018570	Replaced clip and cable rewired connector			2	4	1	5	
0018570	replaced connector						1	
0018570	Replaced emitter					2		
0018572	Rewired components							
0018572	Rewired components and connector							
0018610	Replace clip, connector and cable				1			
0018610	Replaced cable and connector						1	
0018610	Replaced: clip, connector and cable.							
0018610	Replacement already sent out							
0018630	Replaced emitter					2		
0018640	Cable Replaced						1	
0018640	Damaged finger clip							
0018640	Faulty Electronics							
0018640	Intermittant							
0018640	Intermittent							
0018640	No fault found					1	1	
0018640	Red emitter faulty.							
0018640	Replace clip, connector and cable				1			
0018640	Replaced cable and connector						1	
0018640	Replaced clip and cable rewired connector			2	4	1	5	
0018640	Replaced emitter					2		
0018640	Replaced Photodiode							
0018640	Rewired clip replaced cable and connector							
0018650	No fault found					1	1	
0018650	No Fault Return to Stock							
0018650	Replace clip, connector and cable				1			
0018670	Red emitter faulty.							
0018670	Replaced clip and cable rewired connector			2	4	1	5	
0018680	No Fault Return to Stock							
0018700	No Fault Return to Stock							
0018700	Replaced emitter and photodiode							
0018720	Cable Replaced						1	
0018720	No fault found					1	1	
0018720	Replace clip, connector and cable				1			
0018720	Replaced cable and connector						1	
0018720	Replaced clip and cable rewired connector			2	4	1	5	
0018720	replaced connector						1	
0018720	Replaced emitter					2		
0018720	Rewired connector							1
0018730	No Fault Return to Stock							
0018730	Replaced clip and cable rewired connector			2	4	1	5	

Stock Reference	Fault	2005	2006	2007	2008	2009	2010	2011
0018750	Rewired connector							1
0018760	Faulty Electronics							
0018760	No Fault Return to Stock							
0018760	Red emitter faulty.							
0018810	No fault found					1	1	
0018810	Replaced cable and connector						1	
0018820	No fault found					1	1	
0018820	Replaced clip and cable rewired connector			2	4	1	5	
0018820	replaced connector						1	
0018820	Replaced emitter					2		
0018820	Rewired connector							1
0018910	No fault found					1	1	
0018910	Replaced Photodiode							

Comments on Returns:

few repairs compared to sales, no problems found

Comments on Risks with Returns and Potential Re-work:

no risks identified

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

N//A, Due to age and Size of the technical File. SPO2 Probes is still a paper based file.

Comments on Risks with Design Changes:

N//A, Due to age and Size of the technical File. SPO2 Probes is still a paper based file.

Documentation updates / Changes

Comments on Document Changes:

N//A, Due to age and Size of the technical File. SPO2 Probes is still a paper based file.

Comments on Risks with Document Changes:

N//A, Due to age and Size of the technical File. SPO2 Probes is still a paper based file.

Review of Issues

Number of Issues reviewed: 212

Comments on Issues:

no problems found from the Issues system

Comments on Risks with Issues:

No risks identified from 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 :