



16/May/2012

Post market Surveillance and Risk Assessment Re-evaluation

T Adaptors
Viamed 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 / 05 / 12

Stock References Reviewed

Stock Reference	Description
0120100	`T` adapter. 22mm I.D. - 22mm O.D.
0120101	Oxygen sensor adapter cap 22mm I.D.
0120102	Oxygen sensor adapter cap 22mm O.D.
0120103	`T` adapter 15mm paediatric circuits
0120104	`T` adapter. 22mm O.D. - 22mm I.D.
0120105	`T` adapter metal. Model A283.
0120106	`T` adapter. 22mm I.D. - 22mm O.D.
0120107	`T` adapter non rebreathing.
0120108	`T` adapter. 22mm O.D. - 22mm O.D.
0120109	`T` adapter non rebreathing.
0120120	Oxygen concentrator adapter.
0120125	Connector 22mm I.D. - 22mm I.D.
0120126	Connector 22mm O.D. - 22mm O.D.
0120127	Connector 15mm I.D./22mm O.D. - 6.5mm
0120128	Connector - 15mm I.D./22mm I.D. ribbed.
0120129	Connector - 22mm O.D./30mm O.D.
0120130	Connector 15mm O.D. - tapered barbed
0120131	Connector 15mm I.D./22mm O.D. - tapered
0120133	Connector 22mm I.D./30mm O.D. - tapered
0120139	Adapter 15mm I.D. - 10mm I.D.
0120140	Adapter 15mm I.D. - 15mm I.D.
0120141	Adapter 15mm I.D./22mm O.D. -
0120142	Adapter 15mm I.D./22mm O.D. -
0120149	Adapter 15mm I.D. - 10mm I.D.
0120150	Adapter 15mm I.D. - 15mm I.D.
0120151	Adapter 15mm I.D./22mm O.D. -
0120153	Adapter 15mm I.D./22mm O.D. -
0120160	FiO2 sensor adapter.
0120161	FiO2 activator for small bore tubing.
0120162	FiO2 activator for 15mm O2 sensors
0120163	FiO2 activator for 18mm O2 sensors
0120164	Spring loaded FiO2 sensor adapter.
0120165	Replacement `T` assembly for MT 100.
0120166	Replacement activator for MT 100.
0120200	Adult MDI Adapter.
0120201	Adult MDI Adapter.
0120202	Adult MDI Adapter.
0120203	Adult MDI Adapter.
0120204	Paediatric MDI Adapter.
0120205	Paediatric MDI Adapter.
0120206	MDI Adapter - Replacement Rubber Cap.
0120207	MDI Adapter.
0120208	MDI Adapter.
0120300	Wye Connector
0120301	Wye Connector with pressure port.

Stock Reference	Description
0120302	Wye Connector with temperature probe
0120303	Wye Connector with temperature probe
0120304	Temperature probe port cap.
0120305	Wye connector 60 degrees.
0120306	Wye connector 90 degrees.
0120307	Wye connector 60 degrees.
0120310	Auto PEEP measurement device.

Comments on Stock references review:

partnumbers upto date

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0120101	Oxygen sensor adapter cap 22mm I.D.	00009147	Teledyne Analytical Instrument	A
0120102	Oxygen sensor adapter cap 22mm O.D.	00009147	Teledyne Analytical Instrument	A
0120104	`T` adapter. 22mm O.D. - 22mm I.D.	00009147	Teledyne Analytical Instrument	A
0120105	`T` adapter metal. Model A283.	00009147	Teledyne Analytical Instrument	A
0120107	`T` adapter non rebreathing.	00009190	Vandagraph	B
0120120	Oxygen concentrator adapter.	00011712	Maxtec Inc.	B
0120100	`T` adapter. 22mm I.D. - 22mm O.D.	00011844	Instrumentation Industries Inc	B
0120104	`T` adapter. 22mm O.D. - 22mm I.D.	00011844	Instrumentation Industries Inc	B
0120106	`T` adapter. 22mm I.D. - 22mm O.D.	00011844	Instrumentation Industries Inc	B
0120130	Connector 15mm O.D. - tapered barbed	00011844	Instrumentation Industries Inc	B
0120131	Connector 15mm I.D./22mm O.D. - tapered	00011844	Instrumentation Industries Inc	B
0120133	Connector 22mm I.D./30mm O.D. - tapered	00011844	Instrumentation Industries Inc	B
0120139	Adapter 15mm I.D. - 10mm I.D	00011844	Instrumentation Industries Inc	B
0120140	Adapter 15mm I.D. - 15mm I.D	00011844	Instrumentation Industries Inc	B
0120141	Adapter 15mm I.D./22mm O.D. -	00011844	Instrumentation Industries Inc	B
0120153	Adapter 15mm I.D./22mm O.D. -	00011844	Instrumentation Industries Inc	B
0120161	FiO2 activator for small bore tubing.	00011844	Instrumentation Industries Inc	B
0120162	FiO2 activator for 15mm O2 sensors	00011844	Instrumentation Industries Inc	B
0120163	FiO2 activator for 18mm O2 sensors	00011844	Instrumentation Industries Inc	B
0120164	Spring loaded FiO2 sensor adapter.	00011844	Instrumentation Industries Inc	B
0120165	Replacement `T` assembly for MT 100.	00011844	Instrumentation Industries Inc	B
0120166	Replacement activator for MT 100.	00011844	Instrumentation Industries Inc	B
0120201	Adult MDI Adapter.	00011844	Instrumentation Industries Inc	B
0120203	Adult MDI Adapter.	00011844	Instrumentation Industries Inc	B
0120204	Paediatric MDI Adapter.	00011844	Instrumentation Industries Inc	B
0120205	Paediatric MDI Adapter.	00011844	Instrumentation Industries Inc	B

Comments on Suppliers:

supplier reviews are upto date

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0120100	`T` adapter. 22mm I.D. - 22mm O.D.	2070	1708	2747	1947	1689	1920	803
0120101	Oxygen sensor adapter cap 22mm I.D.		3	20	14	4		
0120102	Oxygen sensor adapter cap 22mm O.D.		8	3	5	4		
0120103	`T` adapter 15mm paediatric circuits	2	10	49	18	46	32	22
0120104	`T` adapter. 22mm O.D. - 22mm I.D.	4	8	10	11	4		
0120105	`T` adapter metal. Model A283.							
0120106	`T` adapter. 22mm I.D. - 22mm O.D.			0	5		4	
0120107	`T` adapter non rebreathing.	60		0				
0120108	`T` adapter. 22mm O.D. - 22mm O.D.					3		
0120109	`T` adapter non rebreathing.							
0120120	Oxygen concentrator adapter.	99	10	1	8	23	3	4
0120125	Connector 22mm I.D. - 22mm I.D.					2	15	
0120126	Connector 22mm O.D. - 22mm O.D.	41	35	15	35	41	8	84
0120127	Connector 15mm I.D./22mm O.D. - 6.5mm						6	
0120128	Connector - 15mm I.D./22mm I.D. ribbed.							
0120129	Connector - 22mm O.D./30mm O.D.					2		
0120130	Connector 15mm O.D. - tapered barbed		5			10	15	
0120131	Connector 15mm I.D./22mm O.D. - tapered	10	10	4	90	83	75	7
0120133	Connector 22mm I.D./30mm O.D. - tapered		5	4	91	88	26	7
0120139	Adapter 15mm I.D. - 10mm I.D			250	17		3	5
0120140	Adapter 15mm I.D. - 15mm I.D		2	36	39	31	26	5
0120141	Adapter 15mm I.D./22mm O.D. -			15	120	520	1510	1006
0120142	Adapter 15mm I.D./22mm O.D. -				8			
0120149	Adapter 15mm I.D. - 10mm I.D					1		
0120150	Adapter 15mm I.D. - 15mm I.D						8	
0120151	Adapter 15mm I.D./22mm O.D. -					2	1	3
0120153	Adapter 15mm I.D./22mm O.D. -							12
0120160	FiO2 sensor adapter.		1				3	
0120161	FiO2 activator for small bore tubing.							
0120162	FiO2 activator for 15mm O2 sensors							
0120163	FiO2 activator for 18mm O2 sensors							
0120164	Spring loaded FiO2 sensor adapter.	3	1		13	4		
0120165	Replacement `T` assembly for MT 100.	10				8		
0120166	Replacement activator for MT 100.							
0120200	Adult MDI Adapter.	2						
0120201	Adult MDI Adapter.	50		752	400	200	500	
0120202	Adult MDI Adapter.							
0120203	Adult MDI Adapter.			450				
0120204	Paediatric MDI Adapter.	70						
0120205	Paediatric MDI Adapter.	15		410				
0120206	MDI Adapter - Replacement Rubber Cap.							
0120207	MDI Adapter.							
0120208	MDI Adapter.							
0120300	Wye Connector							
0120301	Wye Connector with pressure port.							
0120302	Wye Connector with temperature probe							

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0120303	Wye Connector with temperature probe							
0120304	Temperature probe port cap.							
0120305	Wye connector 60 degrees.							
0120306	Wye connector 90 degrees.							
0120307	Wye connector 60 degrees.							
0120310	Auto PEEP measurement device.							

Comments on Sales Information:

units still selling, and increaing in sales

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
AU Austria	[X]	[X]	[X]				
B Belgium		[X]			[X]	[X]	
CZ Czech Republic			[X]	[X]		[X]	
DE Denmark	[X]	[X]	[X]	[X]	[X]	[X]	[X]
F France		[X]	[X]	[X]	[X]	[X]	[X]
FI Finland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
G Germany		[X]	[X]	[X]	[X]	[X]	[X]
GR Greece	[X]	[X]	[X]		[X]		
HK Hong Kong	[X]					[X]	
IND Indonesia							[X]
IRE Ireland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
IT Italy		[X]	[X]	[X]	[X]		
J Japan					[X]	[X]	
K Korea			[X]				
LEB Lebanon		[X]		[X]			
MA Malaysia				[X]			
NE Netherlands			[X]			[X]	
NO Norway		[X]		[X]	[X]		
P Poland							
PO Portugal						[X]	
RO Romania					[X]		
RU Russia				[X]	[X]	[X]	[X]
SER Serbia						[X]	
SI Singapore		[X]	[X]				
SW Sweden	[X]	[X]	[X]	[X]	[X]	[X]	
SWI Switzerland							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

IND Indonesia is only new country, still selling units world wide

Comments on Risks with Sales to Countries:

no risks associated with new countrys

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
0120126	No Fault Return to Stock							

Comments on Returns:

no returns 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:

no new design changes

Comments on Risks with Design Changes:

n/a

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
8947	T Adaptors Instructions for Use / User Manual Tapers	18/10/11
729	T Adaptors Instructions for Use / User Manual BE 117 Non Rebreat...	25/09/06

Comments on User Instructions:

user manual was updated

Comments on Risks User Instructions:

no risks associated with new manual

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9169	No accessory labels	18/10/11
7689	T Adaptors Labels	15/02/11

Comments on Labels:

Comments on Risks Labels:

no risks with labels identified

Documentation Updates / Changes

Comments on Document Changes:

lots new documents to bring in line with new essential requirements, no device / substance changes made

Comments on Risks with Document Changes:

no risks found with new documentation

Review of Issues

Number of Issues reviewed: 22

Issue ID	Subject
36353	1969 to 0120126
22778	1969 stock query
30754	small label description removes CE mark on label 0120150
35202	Update Warning Label for 0120100 T Pieces
27617	Controlled Documents require Attention
30115	0120141 stock adjustment
30114	0120141 stock adjustment
35753	MDI adapter pricing review
35752	MDI adapter pricing review
35751	MDI adapter price increase
28828	Price Check
32357	Customer Product Information File Update
28873	Watford adaptors
28872	Adaptor
30721	0120131 none left in ducket
33643	JSC Pro-forma invoice PRO01841
33642	JSC Pro-forma invoice PRO01841
33641	JSC Pro-forma invoice PRO01841
32876	0120151 Steve Hardaker Sales Forcasts
32875	0120141 Steve Hardaker Sales Forcasts
32638	Neopeep & masks requirements for 2012
32637	Neopeep & masks requirements for 2012

Comments on Issues:

no comments on issues,

Comments on Risks with Issues:

no risks found associated to 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 :