



30/Jul/2013

Post market Surveillance and Risk Assessment Re-evaluation

Pulse Oximeter VM-2160
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 30 / 07 / 13

Stock References Reviewed

Stock Reference	Description
0012155	Pulse Oximeter Viamed VM 2160-L.
0012156	Pulse Oximeter Viamed VM 2160-L.
0012157	Pulse Oximeter Viamed VM 2160-L.
0012158	Pulse Oximeter Viamed VM 2160-L.
0012159	Pulse Oximeter Viamed VM 2160-L.
0012160	Pulse Oximeter Viamed VM 2160.
0012161	Pulse Oximeter Viamed VM 2160.
0012162	Pulse Oximeter Viamed VM 2160.
0012163	Pulse Oximeter Viamed VM 2160.
0012164	Pulse Oximeter Viamed VM 2160.
0012165	Pulse Oximeter Viamed VM 2160-D.
0012166	Pulse Oximeter Viamed VM 2160-D.
0012167	Pulse Oximeter Viamed VM 2160-D.
0012168	Pulse Oximeter Viamed VM 2160-D.
0012169	Pulse Oximeter Viamed VM 2160-D.
0012170	Extended warranty - 18 months VM 2160.
0012171	Extended warranty - 24 months VM 2160.
0012190	Pulse Oximeter Viamed VM 2160 - Demo

Comments on Stock references review:

ok

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0012155	Pulse Oximeter Viamed VM 2160-L.	00009300	Bluepoint Medical	A
0012156	Pulse Oximeter Viamed VM 2160-L.	00009300	Bluepoint Medical	A
0012157	Pulse Oximeter Viamed VM 2160-L.	00009300	Bluepoint Medical	A
0012160	Pulse Oximeter Viamed VM 2160.	00009300	Bluepoint Medical	A
0012161	Pulse Oximeter Viamed VM 2160.	00009300	Bluepoint Medical	A
0012162	Pulse Oximeter Viamed VM 2160.	00009300	Bluepoint Medical	A
0012163	Pulse Oximeter Viamed VM 2160.	00009300	Bluepoint Medical	A
0012164	Pulse Oximeter Viamed VM 2160.	00009300	Bluepoint Medical	A
0012190	Pulse Oximeter Viamed VM 2160 - Demo	00009300	Bluepoint Medical	A

Comments on Suppliers:

Still an A rating

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
0012155	Pulse Oximeter Viamed VM 2160-L.			15	3	20	7	
0012156	Pulse Oximeter Viamed VM 2160-L.							
0012157	Pulse Oximeter Viamed VM 2160-L.							
0012158	Pulse Oximeter Viamed VM 2160-L.							
0012159	Pulse Oximeter Viamed VM 2160-L.							
0012160	Pulse Oximeter Viamed VM 2160.	9	179	179	216	154	190	121
0012161	Pulse Oximeter Viamed VM 2160.		73	26	41	144	175	141
0012162	Pulse Oximeter Viamed VM 2160.		58	38	31	27	23	3
0012163	Pulse Oximeter Viamed VM 2160.		5		4			
0012164	Pulse Oximeter Viamed VM 2160.		1		1			
0012165	Pulse Oximeter Viamed VM 2160-D.							
0012166	Pulse Oximeter Viamed VM 2160-D.							
0012167	Pulse Oximeter Viamed VM 2160-D.							
0012168	Pulse Oximeter Viamed VM 2160-D.							
0012169	Pulse Oximeter Viamed VM 2160-D.							
0012170	Extended warranty - 18 months VM 2160.							
0012171	Extended warranty - 24 months VM 2160.							
0012190	Pulse Oximeter Viamed VM 2160 - Demo				1			

Comments on Sales Information:

Sales should be up again year on year

New Countries

Country	2007	2008	2009	2010	2011	2012	2013
AU Austria		[X]	[X]	[X]	[X]	[X]	[X]
B Belgium		[X]	[X]	[X]	[X]	[X]	[X]
CAN Canada			[X]				
CI Canaria Islands		[X]					
CY Cyprus					[X]		
CZ Czech Republic		[X]	[X]				
DE Denmark		[X]	[X]	[X]	[X]	[X]	[X]
F France		[X]		[X]	[X]	[X]	[X]
FI Finland				[X]			
G Germany	[X]	[X]	[X]	[X]	[X]	[X]	[X]
GR Greece		[X]	[X]	[X]	[X]	[X]	[X]
I Iran		[X]	[X]	[X]	[X]	[X]	[X]
IN India		[X]	[X]	[X]		[X]	
IS Israel						[X]	
IT Italy		[X]		[X]			
J Japan		[X]					
JO Jordan			[X]				
KE Kenya		[X]	[X]				
LEB Lebanon		[X]					
MA Malaysia		[X]	[X]	[X]		[X]	
NE Netherlands			[X]	[X]		[X]	
NO Norway			[X]	[X]	[X]	[X]	[X]
OM Oman			[X]	[X]		[X]	[X]
P Poland			[X]	[X]	[X]	[X]	[X]
PO Portugal		[X]	[X]	[X]	[X]	[X]	[X]
RO Romania				[X]	[X]	[X]	[X]
SA South Africa					[X]		
SAU Saudi Arabia		[X]		[X]	[X]	[X]	[X]
SI Singapore				[X]	[X]	[X]	
SP Spain		[X]					
SRI Sri Lanka							[X]
SW Sweden		[X]			[X]	[X]	[X]
SWI Switzerland			[X]		[X]		[X]
SY Syria				[X]			
T Turkey		[X]	[X]	[X]	[X]	[X]	[X]
TH Thailand		[X]	[X]			[X]	[X]
TUN Tunisia		[X]					
UAE U A E						[X]	[X]
UAE U.A.E.		[X]	[X]	[X]	[X]		
UK United Kingdom		[X]	[X]	[X]	[X]	[X]	[X]
VI Vietnam					[X]	[X]	

Comments on Sales to Countries:

Good distribution of countries

Comments on Risks with Sales to Countries:

no new risk identified, Sri Lanka is only new country,

Returns Information

Stock Reference	Fault	2007	2008	2009	2010	2011	2012	2013
0012155	Error message: Device defective			1				
0012155	Keypad fault					3		
0012160	Case fault						2	
0012160	Case refitted				1			
0012160	Customer Declined Quotation				1			
0012160	Data transfer error		1					
0012160	Dead				1	1	2	1
0012160	Display - missing pixels		1					
0012160	Display - speck of dust		1					
0012160	Display fault			2	8	15	9	8
0012160	Error message: Device defective				1			
0012160	Fault code: Sensor fault		1					1
0012160	Faulty probe			1				
0012160	Intermittent						1	
0012160	Keypad fault			3	7	3	1	
0012160	Membrane replaced			6	2			
0012160	No Fault Return to Stock			1	2			
0012160	OLED display faded			1				
0012160	On/off button fault					6	1	
0012160	On/Off button intermittent				1			
0012160	PCB reseated						2	
0012160	QA carried out		1					
0012160	Quote not accepted						2	
0012160	Reprogrammed						1	
0012160	TEST			7	1			
0012160	Upgraded						6	
0012161	Causes error message						1	
0012161	Display fault					1		
0012161	Error message: Device defective		1		1			
0012161	Intermittent						1	
0012161	Keypad fault			1		1		
0012161	On/off button fault					1		
0012161	On/Off button intermittent			1				
0012161	Upgraded						1	
0012162	Display fault		2		1	1	1	
0012162	Keypad fault				1			
0012162	OLED display faded			1				
0012162	On/Off button intermittent		1					
0012162	QA carried out				13			
0012162	Upgraded						2	
0012163	Display fault					1		
0012163	QA carried out				1			
0012164	QA carried out				3			
0012190	No Fault Return to Stock				1			

Comments on Returns:

main fault still seems to be display fault, however its still a very low number of returns so no concerns with quality of product.

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 documents in 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
8275	Pulse Oximeter VM-2160 64Bit USB Driver installation instruction...	11/05/11
5230	VM-2160 Pulse Oximeter Instructions for Use / User Manual Swedis...	17/04/09
5229	VM-2160 Pulse Oximeter Instructions for Use / User Manual Spanis...	17/04/09
5228	VM-2160 Pulse Oximeter Instructions for Use / User Manual Russia...	17/04/09
5227	VM-2160 Pulse Oximeter Instructions for Use / User Manual Portug...	17/04/09
5226	VM-2160 Pulse Oximeter Instructions for Use / User Manual Polish	17/04/09
5225	VM-2160 Pulse Oximeter Instructions for Use / User Manual Hungar...	17/04/09
5224	VM-2160 Pulse Oximeter Instructions for Use / User Manual Greek	17/04/09
5222	VM-2160 Pulse Oximeter Instructions for Use / User Manual Dutch	17/04/09
5221	VM-2160 Pulse Oximeter Instructions for Use / User Manual Danish	17/04/09
5220	VM-2160 Pulse Oximeter Instructions for Use / User Manual Turki...	17/04/09
5219	VM-2160 Pulse Oximeter Instructions for Use / User Manual Itali...	17/04/09
5218	VM-2160 Pulse Oximeter Instructions for Use / User Manual Germa...	17/04/09
5217	VM-2160 Pulse Oximeter Instructions for Use / User Manual Frenc...	17/04/09
5216	VM-2160 Pulse Oximeter Instructions for Use / User Manual Finni...	17/04/09
3951	Pulse Oximeter VM-2160 Instructions for Use /User manual	07/07/08

Comments on User Instructions:

No new Instruction Manuals

Comments on Risks User Instructions:

n/a

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9169	No accessory labels	18/10/11
3950	Pulse Oximeter VM-2160 Labels Outer box main Label	07/07/08
3949	Pulse Oximeter VM-2160 Labels Outer Box	07/07/08
3948	Pulse Oximeter VM-2160 Labels Sensor Cable (2)	07/07/08
3947	Pulse Oximeter VM-2160 Labels Sensor Cable (1)	07/07/08
3946	Pulse Oximeter VM-2160 Labels Back Case	07/07/08

Comments on Labels:

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Comments on Document Changes:

only changes are the yearly pms report and certificate

Comments on Risks with Document Changes:

n/a

Review of Issues

Number of Issues reviewed: 8

Issue ID	Subject
38481	Courier Cost - UAE
38480	Courier Cost - UAE
43261	Returned Items SOR511
42869	Returned Items SOR546
37465	Images not displaying correctly
39106	I0007224 - Cortessis Medical tender 0012160
38517	0092174 - Leaflet - Pulse Oximetry Accessories
40286	Ata Medikal - VM2160 (0012162)

Comments on Issues:

No problem Issues identified

Comments on Risks with Issues:

n/a

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 :

nothing new found,
spo2 monitoring is well established

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 :

Only incident found was a N560 nellcor where the audio had failed,
no other reports found.