



16/May/2012

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 16 / 05 / 12

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:

no new part numbers

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:

supplier review upto date

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0012155	Pulse Oximeter Viamed VM 2160-L.				15	3	20	
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	90
0012161	Pulse Oximeter Viamed VM 2160.			73	26	41	144	89
0012162	Pulse Oximeter Viamed VM 2160.			58	38	31	27	9
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:

units still selling, and should be up on last year

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
AU Austria			[X]	[X]	[X]	[X]	[X]
B Belgium			[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]
F France			[X]		[X]	[X]	[X]
FI Finland					[X]		
G Germany		[X]	[X]	[X]	[X]	[X]	[X]
GR Greece			[X]	[X]	[X]	[X]	[X]
I Iran			[X]	[X]	[X]	[X]	
IN India			[X]	[X]	[X]		
IT Italy			[X]		[X]		
J Japan			[X]				
JO Jordan				[X]			
KE Kenya			[X]	[X]			
LEB Lebanon			[X]				
MA Malaysia			[X]	[X]	[X]		
NE Netherlands				[X]	[X]		[X]
NO Norway				[X]	[X]	[X]	
OM Oman				[X]	[X]		[X]
P Poland				[X]	[X]	[X]	[X]
PO Portugal			[X]	[X]	[X]	[X]	[X]
RO Romania					[X]	[X]	[X]
SA South Africa						[X]	
SAU Saudi Arabia			[X]		[X]	[X]	
SI Singapore					[X]	[X]	[X]
SP Spain			[X]				
SW Sweden			[X]			[X]	[X]
SWI Switzerland				[X]		[X]	
SY Syria					[X]		
T Turkey			[X]	[X]	[X]	[X]	[X]
TH Thailand			[X]	[X]			[X]
TUN Tunisia			[X]				
UAE U.A.E.			[X]	[X]	[X]	[X]	[X]
UK United Kingdom			[X]	[X]	[X]	[X]	[X]
VI Vietnam						[X]	

Comments on Sales to Countries:

Still selling world wide, no new countries have been sold to

Comments on Risks with Sales to Countries:

no risks associated with countries

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
0012155	Error message: Device defective				1			
0012155	Keypad fault						3	
0012160	Case refitted					1		
0012160	Customer Declined Quotation					1		
0012160	Data transfer error			1				
0012160	Dead					1	1	
0012160	Display - missing pixels			1				
0012160	Display - speck of dust			1				
0012160	Display fault				2	8	15	1
0012160	Error message: Device defective					1		
0012160	Fault code: Sensor fault			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	
0012160	On/Off button intermittent					1		
0012160	QA carried out			1				
0012160	Quote not accepted							2
0012160	TEST				7	1		
0012160	Upgraded							6
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		
0012163	Display fault						1	
0012163	QA carried out					1		
0012164	QA carried out					3		
0012190	No Fault Return to Stock					1		

Comments on Returns:

limited number returns, most were for software upgrade

Comments on Risks with Returns and Potential Re-work:

no risks associated with returns

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no documents added to 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:

upgrade instructions added

Comments on Risks User Instructions:

no risks with new instructions

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:

no risks with labels

Documentation Updates / Changes

Comments on Document Changes:

new documentation added to comply with new essential requirements

Comments on Risks with Document Changes:

no risks with new documentstion

Review of Issues

Number of Issues reviewed: 10

Issue ID	Subject
35783	Courier Cost to Benin
35455	Returned Items SOR452
33921	Returned Items SOR414
33522	Returned Items SOR471
32732	Replacement for 0012163
33848	need two probes taking out of merge stock
34219	0012160 Derek Lamb Sales Forecasts
34218	0012160 Derek Lamb Sales Forecasts
32138	Web site images
29584	Web site edits - Pulse Oximeters

Comments on Issues:

no problems with issues

Comments on Risks with Issues:

no risks found with 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 :

vague search, lots found on pulse oximetry too many to narrow down,
but indicates technology not out of date

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 :

no reports found