



24/Mar/2011

Pulse Oximeter VM2101 F

Pulse Oximeter VM2101 Finger SpO2
Viamed OBL product
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 / 03 / 11

Stock References Reviewed

Stock Reference	Description
0012101	Finger Pulse Oximeter Viamed VM 2101.
0012102	Finger Pulse Oximeter Viamed VM 2101.

Comments on Stock references review:

0012102 is Exatly same as 0012101, different part number was used as a Specfic customer got a 1 off special price with a different warranty period to the 0012101

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0012101	Finger Pulse Oximeter Viamed VM 2101.	00009300	Bluepoint Medical	A

Comments on Suppliers:

supplier has been reviewed

Sales Information

Stock Reference	Description	2005	2006	2007	2008	2009	2010	2011
0012101	Finger Pulse Oximeter Viamed VM 2101.				254	1653	1009	169
0012102	Finger Pulse Oximeter Viamed VM 2101.					1356	1	

Comments on Sales Information:

Units still being sold

New Countries

Country	2005	2006	2007	2008	2009	2010	2011
AU Austria				[X]	[X]		
B Belgium				[X]	[X]	[X]	[X]
CAN Canada					[X]		
CRO Croatia				[X]			
CY Cyprus							[X]
CZ Czech Republic				[X]			
DE Denmark				[X]			
EG Egypt					[X]		
ES Estonia					[X]	[X]	
FI Finland					[X]	[X]	[X]
G Germany				[X]	[X]		[X]
GEO Georgia						[X]	
GR Greece				[X]	[X]	[X]	
I Iran				[X]	[X]	[X]	
IN India				[X]	[X]	[X]	
IRE Ireland				[X]			
JO Jordan					[X]		
KE Kenya				[X]	[X]	[X]	
KU Kuwait					[X]		
LEB Lebanon					[X]		
MA Malaysia				[X]	[X]		
NE Netherlands					[X]		
NO Norway					[X]	[X]	[X]
OM Oman					[X]	[X]	
P Poland					[X]	[X]	[X]
PO Portugal				[X]	[X]	[X]	
RO Romania					[X]	[X]	
SAU Saudi Arabia					[X]		
SI Singapore					[X]		
SP Spain					[X]	[X]	
SWI Switzerland				[X]		[X]	
T Turkey				[X]			
TH Thailand					[X]		
UAE U.A.E.					[X]	[X]	
UK United Kingdom				[X]	[X]	[X]	[X]
USA U.S.A.					[X]		

Comments on Sales to Countries:

Cyprus is the only new country<
Units are still being sold internationally

Comments on Risks with Sales to Countries:

No risks with countries units are being sold into

Returns Information

Stock Reference	Fault	2005	2006	2007	2008	2009	2010	2011
0012101	Dead						3	2
0012101	Display fault					1	3	
0012101	False reading						3	2
0012101	Intermittent					1		
0012101	No Fault Return to Stock					2		
0012101	PCB damaged						1	
0012101	Picking up false signal					1		
0012101	Rewired					2	1	
0012101	Spring missing						5	2
0012101	TEST				1		7	
0012101	Unit dead					1		
0012101	Unrepaired					1		
0012102	Display fault					1	3	
0012102	Picking up false signal					1		
0012102	Spring missing						5	2

Comments on Returns:

Returns are very low < 1 % for both models

Comments on Risks with Returns and Potential Re-work:

No risks with reworks as units,

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes have occurred

Comments on Risks with Design Changes:

Documentation updates / Changes

Comments on Document Changes:

Various documents have been updated

Comments on Risks with Document Changes:

no risks associated with updated documents

Review of Issues

Number of Issues reviewed: 47

Comments on Issues:

Issues reviewed, mostly SOR or stock movements,

Comments on Risks with Issues:

no risks were identified from the 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 :

Various clinicla reports have shown up, most related to different subject matter (e.g. sleep studies) as opposed to the units themselves,

No risks were identified

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 specific incident reports were found