



16/Jan/2014

Post market Surveillance and Risk Assessment Re-evaluation

Pulse Oximeter VM2105 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
User Manuals Review
Labels Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 16 / 01 / 14

Stock References Reviewed

Stock Reference	Description
0012103	Finger Pulse Oximeter Viamed VM 2103.
0012105	Finger Pulse Oximeter Viamed VM 2105.
0012106	Finger Pulse Oximeter Viamed VM 2105.

Comments on Stock references review:

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0012103	Finger Pulse Oximeter Viamed VM 2103.	00009300	Bluepoint Medical	A
0012105	Finger Pulse Oximeter Viamed VM 2105.	00009300	Bluepoint Medical	A
0012106	Finger Pulse Oximeter Viamed VM 2105.	00009300	Bluepoint Medical	A

Comments on Suppliers:

Suppliers certificates still in date,
Still A rated

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0012103	Finger Pulse Oximeter Viamed VM 2103.					15	54	2
0012105	Finger Pulse Oximeter Viamed VM 2105.		140	123	294	242	91	1
0012106	Finger Pulse Oximeter Viamed VM 2105.		145	35	14	20	37	1

Comments on Sales Information:

Units still selling, sharp drop in 0012105 tho.

New Countries

Country	2008	2009	2010	2011	2012	2013	2014
AU Austria		[X]				[X]	
B Belgium		[X]	[X]	[X]		[X]	
CAN Canada		[X]					
CI Canaria Islands				[X]			
CY Cyprus				[X]			
CZ Czech Republic		[X]		[X]	[X]	[X]	
DE Denmark		[X]		[X]			
EG Egypt		[X]		[X]			
ES Estonia			[X]	[X]		[X]	
F France		[X]	[X]			[X]	[X]
FI Finland		[X]	[X]	[X]	[X]	[X]	
G Germany							
GR Greece		[X]					
IND Indonesia						[X]	
IQ IRAQ					[X]		
IRE Ireland						[X]	
IS Israel		[X]		[X]			
IT Italy						[X]	
J Japan		[X]			[X]		
KE Kenya			[X]				
KU Kuwait				[X]			
LEB Lebanon					[X]		
NE Netherlands		[X]					
NO Norway		[X]	[X]	[X]	[X]	[X]	
OM Oman		[X]	[X]			[X]	
P Poland		[X]				[X]	
PO Portugal		[X]	[X]	[X]			
SA South Africa				[X]	[X]		
SAU Saudi Arabia			[X]	[X]		[X]	
SI Singapore		[X]					
SL Slovenia			[X]				
SP Spain		[X]	[X]	[X]			
SW Sweden				[X]			
SWI Switzerland		[X]	[X]	[X]	[X]	[X]	
TH Thailand		[X]		[X]			
UAE U.A.E.		[X]	[X]				
UK United Kingdom		[X]	[X]	[X]	[X]	[X]	
USA USA					[X]		

Comments on Sales to Countries:

Indonesia, Ireland, Italy
New countries being sold to,

Comments on Risks with Sales to Countries:

No risks identified with new countries

Returns Information

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0012103	False reading					3		
0012105	Battery lead fault				14			
0012105	Dead			2		3		
0012105	Display fault				2		1	
0012105	False reading		1	1	3			
0012105	Faulty Electronics		1					
0012105	Faulty probe		1	4	1			
0012105	High reading				3			
0012105	Intermittent		1	1	1			
0012105	Intermittent When Squeezed			2				
0012105	No Fault Found			1	2			
0012105	No Fault Return to Stock			1				
0012105	Picking up false signal		1					
0012105	Rewired			1				
0012105	TEST			1				
0012105	Tested OK				2			
0012105	Unchecked - Returned to Stock							
0012105	Unit dead		1					
0012106	Battery lead fault			2	3			
0012106	Battery wires broken						1	
0012106	Case fault			1				
0012106	Dead			3		2		
0012106	Display fault			1				
0012106	False reading		2	8	1	3	1	
0012106	Faulty Electronics		1					
0012106	Faulty probe			2	1			
0012106	High reading				1			
0012106	Intermittent When Squeezed			1				
0012106	Orange VM2105 problem			12				
0012106	Picking up false signal			1				
0012106	TEST		1	1				
0012106	Unable to switch on			1				
0012106	Uneconomical to repair			1				

Comments on Returns:

Very small number faults.

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 design changes have taken place

Comments on Risks with Design Changes:

n/a

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
6976	VM 2105 Instruction Manual Spanish	17/03/10
6975	VM 2105 Instruction Manual German	17/03/10
6974	VM 2105 Instruction Manual French	17/03/10
6973	VM 2105 Instruction Manual English	17/03/10
5080	VM-2105 Finger Oximeter Quick Start Guide Document	17/02/09

Comments on User Instructions:

No updates to user instructions

Comments on Risks User Instructions:

n/a

Labels

Showing Documents Filed in F 7 / F 8 Labels

Comments on Labels:

no changes to labels

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Comments on Document Changes:

No significant changes to the documentation

Comments on Risks with Document Changes:

n/a

Review of Issues

Number of Issues reviewed: 9

Issue ID	Subject
46417	Returned Items SOR578
45590	Yorkshire Ambulance consignment stock levels
45589	Yorkshire Ambulance consignment stock levels
45588	Yorkshire Ambulance consignment stock levels
45587	Yorkshire Ambulance consignment stock levels
45586	Yorkshire Ambulance consignment stock levels
44304	Yorkshire Ambulance Consignment Stock
41234	AH - Spengler
36465	Finger oximeter - India special prices

Comments on Issues:

Stock Issues, and pricing queries, found in the Issues system.

Comments on Risks with Issues:

No risks identified in 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 :