



12/Mar/2012

## Post market Surveillance and Risk Assessment Re-evaluation

Temperature Probes BPM
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 12 / 03 / 12

## Stock References Reviewed

Stock Reference	Description
0212009	Temperature probe - Oesophageal/Rectal.
0212010	Temperature probe - Oesophageal/Rectal.
0212011	Temperature probe - Oesophageal/Rectal.
0212012	Temperature probe - Oesophageal/Rectal.
0212013	Temperature probe - Oesophageal/Rectal.
0212014	Temperature probe - Oesophageal/Rectal.
0212015	Temperature probe - Oesophageal/Rectal.
0212016	Temperature probe - Oesophageal/Rectal.
0212017	Temperature probe - Oesophageal/Rectal.
0212018	Temperature probe - Oesophageal/Rectal.
0212019	Temperature probe - Oesophageal/Rectal.
0212020	Temperature probe - Oesophageal/Rectal.
0212021	Temperature probe - Skin contact.
0212022	Temperature probe - Skin contact.
0212023	Temperature probe - Skin contact.
0212024	Temperature probe - Skin contact.
0212025	Temperature probe - Skin contact.
0212026	Temperature probe - Skin contact.
0212027	Temperature probe - Skin contact.
0212028	Temperature probe - Skin contact.
0212029	Temperature probe - Skin contact.
0212030	Temperature probe - Skin contact.
0212031	Temperature probe - Skin contact.
0212032	Temperature probe - Skin contact.
0222000	Temperature probe - Series 400-AC
0222001	Temperature probe - Series 400-AC

Comments on Stock references review:

added all numbers, - First PMS to be done on this File

## Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0212009	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212010	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212011	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212012	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212013	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212014	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212015	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212016	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212017	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212018	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212019	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212020	Temperature probe - Oesophageal/Rectal.	00009300	Bluepoint Medical	A
0212021	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212022	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212023	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212024	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212025	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212026	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212027	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212028	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212029	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212030	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212031	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0212032	Temperature probe - Skin contact.	00009300	Bluepoint Medical	A
0222000	Temperature probe - Series 400-AC	00009300	Bluepoint Medical	A
0222001	Temperature probe - Series 400-AC	00009300	Bluepoint Medical	A

Comments on Suppliers:

OBL from Bluepoint.Rating is valid

## Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
0212009	Temperature probe - Oesophageal/Rectal.			11		6	1	
0212010	Temperature probe - Oesophageal/Rectal.			10		0	5	
0212011	Temperature probe - Oesophageal/Rectal.			11			1	
0212012	Temperature probe - Oesophageal/Rectal.			1				
0212013	Temperature probe - Oesophageal/Rectal.			4				
0212014	Temperature probe - Oesophageal/Rectal.			4	1		5	
0212015	Temperature probe - Oesophageal/Rectal.							
0212016	Temperature probe - Oesophageal/Rectal.		1					
0212017	Temperature probe - Oesophageal/Rectal.			5				
0212018	Temperature probe - Oesophageal/Rectal.							
0212019	Temperature probe - Oesophageal/Rectal.							
0212020	Temperature probe - Oesophageal/Rectal.			10	10	2	7	
0212021	Temperature probe - Skin contact.			5				3
0212022	Temperature probe - Skin contact.				10	1		
0212023	Temperature probe - Skin contact.			6	1			
0212024	Temperature probe - Skin contact.							
0212025	Temperature probe - Skin contact.							
0212026	Temperature probe - Skin contact.				1			
0212027	Temperature probe - Skin contact.			2				
0212028	Temperature probe - Skin contact.			4				
0212029	Temperature probe - Skin contact.			2				
0212030	Temperature probe - Skin contact.			2		1		
0212031	Temperature probe - Skin contact.			2	1	1	1	
0212032	Temperature probe - Skin contact.			2				
0222000	Temperature probe - Series 400-AC							
0222001	Temperature probe - Series 400-AC							

Comments on Sales Information:

Sales very Low, and virtually non existant

## New Countries

Country	2006	2007	2008	2009	2010	2011	2012
AU Austria			[X]				
CH Chile					[X]	[X]	
GR Greece			[X]				
IN India			[X]				
IS Israel				[X]	[X]	[X]	
MA Malaysia				[X]			
P Poland						[X]	
PO Portugal				[X]			
T Turkey			[X]				
UK United Kingdom		[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

No comments

Comments on Risks with Sales to Countries:

No risks identified with current range of countries

## Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
0212010	No Fault Return to Stock							
0212020	Cable open circuit							

Comments on Returns:

Very low number of faults ( taking note sales number have been low)

Comments on Risks with Returns and Potential Re-work:

No return / rework carried out.faulty product would be returned to BPM,No risks identified

## Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No Comments - No documents

Comments on Risks with Design Changes:

No Comments - No documents

## Documentation updates / Changes

Comments on Document Changes:

First pms review all files appear new

Comments on Risks with Document Changes:

No identified risk with new files.



## Review of Issues

Number of Issues reviewed: 10

Comments on Issues:

10 new Issues,&nbsp;Mainly sale return issues,and the setting up of lables require for the OBL

Comments on Risks with Issues:

No Risks identified

## 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 found to indicate a risk with the temperature probes

Temperature probes are still current technology

## 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 :

Nothing found