



VIA MED

Pulse Oximeter VM-2160

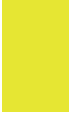
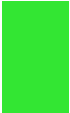
Handheld pulse oximeter for continuous and spot-check monitoring of functional arterial oxygen saturation (SpO₂) and pulse rate,

Class IIa
Via Rule 10
Assesment Route Annex II
NBOG MD1302

Carried out by Derek Lamb
16 / 09 / 14



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
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-  Design Changes Review
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-  Internal Issues Review
-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

Stock References Review

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.
0012175	Pulse Oximeter Viamed VM 2160.
0012176	Pulse Oximeter Viamed VM 2160.
0012177	Pulse Oximeter Viamed VM 2160.
0012178	Pulse Oximeter Viamed VM 2160.
0012179	Pulse Oximeter Viamed VM 2160.
0012189	Pulse Oximeter Viamed VM 2160-L - Demo
0012190	Pulse Oximeter Viamed VM 2160 - Demo

Comments on Stock references review:

Part number checked and upto date

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier P/N	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	1020112003	Bluepoint Medical	A
0012161	Pulse Oximeter Viamed VM 2160.	00009300	1020112003 SCAND	Bluepoint Medical	A
0012162	Pulse Oximeter Viamed VM 2160.	00009300	1020112003 EU SC	Bluepoint Medical	A
0012163	Pulse Oximeter Viamed VM 2160.	00009300	1020112003 A I	Bluepoint Medical	A
0012164	Pulse Oximeter Viamed VM 2160.	00009300	1020112003 A II	Bluepoint Medical	A
0012175	Pulse Oximeter Viamed VM 2160.	00009300	4020112003	Bluepoint Medical	A
0012190	Pulse Oximeter Viamed VM 2160 - Demo	00009300		Bluepoint Medical	A

Comments on Suppliers:

Supplier review is up to date

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
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.	183	185	216	154	190	375	67
0012161	Pulse Oximeter Viamed VM 2160.	73	26	41	164	177	254	118
0012162	Pulse Oximeter Viamed VM 2160.	58	38	31	27	23	35	32
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.							
0012175	Pulse Oximeter Viamed VM 2160.				22	45	54	29
0012176	Pulse Oximeter Viamed VM 2160.							
0012177	Pulse Oximeter Viamed VM 2160.							
0012178	Pulse Oximeter Viamed VM 2160.							
0012179	Pulse Oximeter Viamed VM 2160.							
0012189	Pulse Oximeter Viamed VM 2160-L - Demo							
0012190	Pulse Oximeter Viamed VM 2160 - Demo			1				

Comments on Sales Information:

Units still selling, however the numbers appear to be dropping

Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
AU Austria	[X]	[X]	[X]	[X]	[X]	[X]	[X]
B Belgium	[X]	[X]	[X]	[X]	[X]	[X]	[X]
CAN Canada		[X]					
CI Canary Islands	[X]						
CY Cyprus				[X]			
CZ Czech Republic	[X]	[X]					
DE Denmark	[X]	[X]	[X]	[X]	[X]	[X]	[X]
ES Estonia							[X]
F France	[X]		[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]	[X]
I Iran	[X]	[X]	[X]	[X]	[X]	[X]	
IN India	[X]	[X]	[X]		[X]		
IND Indonesia						[X]	
IQ IRAQ						[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]	[X]	
NE Netherlands		[X]	[X]		[X]		
NO Norway		[X]	[X]	[X]	[X]	[X]	[X]
OM Oman		[X]	[X]		[X]	[X]	
P Poland		[X]	[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]	[X]
SI Singapore			[X]	[X]	[X]		
SP Spain	[X]					[X]	
SRI Sri Lanka						[X]	[X]
SW Sweden	[X]			[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]	[X]	[X]	[X]	[X]	[X]
UG UGANDA						[X]	

Country	2008	2009	2010	2011	2012	2013	2014
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
VI Vietnam				[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Estonia Indonesia IRAQ UGANDA, are new countries,

Comments on Risks with Sales to Countries:

No risks identified with the new countries

Returns Review

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0012155	Display fault							1
0012155	Error message: Device defective		1					
0012155	Keypad fault				3			
0012155	No Fault Found				1	2		
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	10	3
0012160	Error message: Device defective			1				
0012160	Fault code: Sensor fault	1					1	2
0012160	Faulty probe		1					
0012160	Intermittent					1		
0012160	Keypad fault		3	7	3	1		
0012160	Membrane replaced		6	2				
0012160	No Fault Found	1	1	4		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		1
0012160	QA carried out	1						
0012160	Quote not accepted					2	1	
0012160	Reprogrammed					1		
0012160	TEST		7	1				
0012160	Unchecked - Returned to Stock							
0012160	Upgraded					6		
0012161	Causes error message					1		
0012161	Dead							1
0012161	Display fault				1			1
0012161	Error message: Device defective	1		1				
0012161	Intermittent					1		
0012161	Keypad fault		1		1			1
0012161	No Fault Found				2	2	4	
0012161	On/off button fault				1			
0012161	On/Off button intermittent		1					
0012161	Unable to switch on							1
0012161	Upgraded					1		
0012162	Display fault	2		1	1	1		

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0012162	Keypad fault			1				
0012162	No Fault Found		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				
0012175	Dead							1
0012175	Device Defective						1	
0012175	No Fault Return to Stock						1	
0012175	Unable to switch on						1	
0012175	Uneconomical to repair						1	
0012175	Upgraded					1		
0012190	No Fault Return to Stock			1				

Comments on Returns:

closer inspection to the 0012160 as it reads a 9% return rate.
on review its a 7.2% true fault return.
of that 3.6% were a display fault from a batch of displays.
fault has since been fixed

Comments on Risks with Returns and Potential Re-work:

No patient risks identified from the faults.

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Design changes held off-site at OEM company

Comments on Risks with Design Changes:

User Instructions Review

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 user instructions have been uploaded

Comments on Risks User Instructions:

n/a

Labels Review

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:

Labels have not changed since the last review

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
13684	Pulse Oximeter VM-2160 EMC report 0012160	08/05/14
13446	Pulse Oximeter VM-2160 EN Standards ISO 9919 (Drop Test)	02/04/14
13168	CE 540537 Certificate Customer Copy	22/11/13
13136	Generic CE File Attached to All Medicinal Substances None	31/10/13
13135	No Animal Tissues No Animal Substances	31/10/13
13117	Pulse Oximeter VM-2160 External Test Results certificate enviro...	25/10/13
13093	Pulse Oximeter VM-2160 OES (OEM) Instructions for Use	16/10/13
12812	Pulse Oximeter VM-2160 Clinical Trials Reports Reviews and Post ...	30/07/13

Comments on Document Changes:

No major new documents added to the system.

Comments on Risks with Document Changes:

no risk identified with new documentation

Internal Issues Review

Number of Issues reviewed: 28

Issue ID	Subject
47445	Proforma for ex-demo VM-2160
51371	Returned Items SOR599
50739	Further testing information - MAX250(B) on SRS64344
50199	Document Update Request
51507	Contact Details Update
51506	Contact Details Update
51505	Contact Details Update
51504	Contact Details Update
51503	Contact Details Update
47654	Contact Details Update
47814	Ingress Protection Rating - Water Ingress
47813	Ingress Protection Rating - Water Ingress
47812	Ingress Protection Rating - Water Ingress
47811	Ingress Protection Rating - Water Ingress
47810	Ingress Protection Rating - Water Ingress
47809	Ingress Protection Rating - Water Ingress
47808	Ingress Protection Rating - Water Ingress
47807	Ingress Protection Rating - Water Ingress
47806	Ingress Protection Rating - Water Ingress
47805	Ingress Protection Rating - Water Ingress
47804	Ingress Protection Rating - Water Ingress
47803	Ingress Protection Rating - Water Ingress
47802	Ingress Protection Rating - Water Ingress
47800	Ingress Protection Rating - Water Ingress
47799	IPXX Ratings - Ingress Protection
47798	IPXX Ratings - Ingress Protection
47797	IPXX Ratings - Ingress Protection
51649	0012101 & 0012175 stock levels

Comments on Issues:

Ignore all contact update issues - seems the Opera Account number, matches the part number of a 0012163. so the system has flagged for review in error.

Rest mainly sales and marketing issues

Comments on Risks with Issues:

no risks identified in the Issues system

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Pulse oximetry is globally used technology is current and upto 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 :

Risk ISO 14971 : 2012 Review

Full ISO 14971 : 2012 Risk review held off-site at original OEM company