



VIA MED

Pulse Oximeter VM2101 Finger SpO₂

Finger oximeter for monitoring of functional arterial
oxygen saturation (SpO₂) and pulse rate,

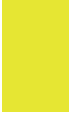
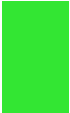
Class IIb

NBOG MD1302

Carried out by Derek Lamb
20 / 04 / 16



VIA MED

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Stock References Review

Stock Reference	Description
0012101	Finger Pulse Oximeter Viamed VM 2101.
0012102	Finger Pulse Oximeter Viamed VM 2101.
0012103	Finger Pulse Oximeter Viamed VM 2103.
0012105	Finger Pulse Oximeter Viamed VM 2105.
0012106	Finger Pulse Oximeter Viamed VM 2105.
0012186	Finger Pulse Oximeter VM 2101 - Demo.
0022190	Soft Carrying Case (Black).
0022191	Soft Carrying Case (Orange).
0022192	Soft Carrying Case (Green).
0022193	Soft Carrying Case (Blue).

Comments on Stock references review:

added the 0012105 series as the reports are same as 0012101 series

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0012101	Finger Pulse Oximeter V	00009300	2020112002	Bluepoint Medical	A
0012103	Finger Pulse Oximeter V	00009300		Bluepoint Medical	A
0012105	Finger Pulse Oximeter V	00009300	2020112003	Bluepoint Medical	A
0012106	Finger Pulse Oximeter V	00009300		Bluepoint Medical	A
0012186	Finger Pulse Oximeter V	00009300		Bluepoint Medical	A
0022190	Soft Carrying Case (Blac	00012322		Beijing Choice Electroni	B
0022191	Soft Carrying Case (Oran	00012322		Beijing Choice Electroni	B
0022192	Soft Carrying Case (Gree	00012322		Beijing Choice Electroni	B
0022193	Soft Carrying Case (Blue	00012322		Beijing Choice Electroni	B

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0012101	Finger Pulse Oximeter V	1321	1008	669	511	615	605	82
0012102	Finger Pulse Oximeter Viamed VM 2101.	1						
0012103	Finger Pulse Oximeter V			15	54	45	5	
0012105	Finger Pulse Oximeter V	151	367	242	91	57	58	15
0012106	Finger Pulse Oximeter V	57	26	20	37	23	0	32
0012186	Finger Pulse Oximeter V	1						
0022190	Soft Carrying Case (Blac	623	202	165	38	209	26	5
0022191	Soft Carrying Case (Oran	189	233	338	51	67	56	
0022192	Soft Carrying Case (Gree	53	78	98	54	10	3	2
0022193	Soft Carrying Case (Blue							1

Comments on Sales Information:

units still selling

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
AU Austria				[X]	[X]	[X]	
B Belgium	[X]	[X]	[X]	[X]	[X]		
CAN Canada							
CI Canary Islands		[X]	[X]				
CRO Croatia							
CY Cyprus		[X]			[X]		
CZ Czech Republic		[X]	[X]	[X]	[X]	[X]	
DE Denmark		[X]					
EG Egypt		[X]					
ES Estonia	[X]	[X]	[X]	[X]	[X]	[X]	
F France	[X]	[X]	[X]	[X]	[X]		
FI Finland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
G Germany		[X]	[X]	[X]			
GEO Georgia	[X]						
GR Greece	[X]	[X]	[X]	[X]	[X]	[X]	
I Iran	[X]	[X]	[X]	[X]			
IN India	[X]	[X]				[X]	
IND Indonesia				[X]			
IQ IRAQ			[X]	[X]			
IRE Ireland				[X]		[X]	
IS Israel		[X]			[X]		
IT Italy				[X]			
J Japan			[X]				
JO Jordan							
KE Kenya	[X]						
KU Kuwait		[X]			[X]	[X]	
LEB Lebanon			[X]				
LI Lithuania			[X]				
MA Malaysia			[X]				
NE Netherlands							
NO Norway	[X]	[X]	[X]	[X]	[X]		
OM Oman	[X]	[X]	[X]	[X]	[X]	[X]	[X]
P Poland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
PO Portugal	[X]	[X]					
RO Romania	[X]				[X]	[X]	
SA South Africa		[X]	[X]				
SAU Saudi Arabia	[X]	[X]		[X]			
SI Singapore							
SL Slovenia	[X]						
SP Spain	[X]	[X]			[X]		
SW Sweden		[X]			[X]		
SWI Switzerland	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Country	2010	2011	2012	2013	2014	2015	2016
T Turkey							
TH Thailand		[X]					
UAE U A E	[X]			[X]	[X]	[X]	
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA			[X]				

Comments on Sales to Countries:

no new countries added to the list

Comments on Risks with Sales to Countries:

no risk identified with countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0012101	Dead	3	2		4			
0012101	Device Defective					1		
0012101	Display fault	3	5	2	1	1	3	
0012101	False reading	3	5	4	1			
0012101	Faulty probe			1				
0012101	High reading		1					
0012101	Intermittent							
0012101	No Fault Found	3	1	1				
0012101	No Fault Return to Stock							
0012101	PCB damaged	1						
0012101	Picking up false signal							
0012101	Rewired	1	1					
0012101	Spings missing/detached			1				
0012101	Spring missing	5	5				6	
0012101	Springs replaced					1		
0012101	TEST	7						
0012101	Unchecked - Returned to Stock							
0012101	Uneconomical to repair				2			
0012101	Unit dead		1					
0012101	Unrepaired							
0012102	Display fault	2						
0012102	Picking up false signal							
0012102	Spring missing	1						
0012103	False reading			3				
0012105	Battery lead fault		14			1		
0012105	Dead	2		3				
0012105	Display fault		2		1	1		
0012105	False reading	1	3					
0012105	Faulty Electronics							
0012105	Faulty probe	4	1					
0012105	High reading		3					
0012105	Intermittent	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							
0012105	Rewired	1						
0012105	TEST	1						
0012105	Tested OK		2					
0012105	Unchecked - Returned to Stock							
0012105	Unit dead							
0012106	Battery lead fault	2	3					

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0012106	Battery wires broken				1			
0012106	Case fault	1						
0012106	Dead	3		2				
0012106	Display fault	1						
0012106	False reading	8	1	3	1			
0012106	Faulty Electronics							
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						
0012106	Unable to switch on	1						
0012106	Unchecked - Returned to Stock							
0012106	Uneconomical to repair	1						
0012186	No Fault Return to Stock	1						
0022190	Physically broken	1						

Comments on Returns:

very low returns rate,

Comments on Risks with Returns and Potential Re-work:

no risks identified with the returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

n/a no design changes

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
5078	VM-2101 Finger Oximeter Quick Start Guide	17/02/09
4744	VM-2101 User Instructions German	13/10/08
4743	VM-2101 User Instructions Spanish	13/10/08
4741	VM-2101 User Instructions French	13/10/08
4740	VM-2101 User Instructions English	13/10/08

Comments on User Instructions:

no changes to the IFU

Comments on Risks User Instructions:

no risks identified with IFU

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
4676	Pulse Oximeter VM2101 Finger SpO2 Labels tracking label	12/09/08
4675	Pulse Oximeter VM2101 Finger SpO2 Labels rear label	12/09/08
4674	Pulse Oximeter VM2101 Finger SpO2 Labels box label - rear	12/09/08
4673	Pulse Oximeter VM2101 Finger SpO2 Labels box labe - side	12/09/08

Comments on Labels:

no immediate changes to the labels, although a new label is due with the blue man Icon

Comments on Risks Labels:

no risks with the labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
15418	PPE Equipment	11/08/15
15009	Competitor Product MHRA FDA Field Safety Notices Covidien Displa...	26/05/15
14886	Capnograph Expected Life of Products Various Products Blue poin...	27/03/15
14602	BPM Annex II BPM Notified body certification Blue Point EC Certi...	10/12/14
14276	Pulse Oximeter VM2101 Finger SpO2 Clinical Trials Reports Review...	16/09/14

Comments on Document Changes:

no real document changes

Comments on Risks with Document Changes:

no risks identified with new documents added

Internal Issues Review

Number of Issues reviewed: 77

Issue ID	Subject
63052	0012101 Price USD End User request Large Quantity
52958	0012101 QA
56568	0012101, 0012105
59779	0012105 and 0012106 - Incorrect price breaks
52016	Auto move QA items to stock shelf
59544	Backorder 00000044 0012101 ORD74496
58275	Backorder 00000131 0012101 ORD73714
56998	Backorder 00000580 0012101 ORD72916
70204	Backorder 00000598 0012101 ORD79838
67895	Backorder 00000950 0012101 ORD78896
59301	Backorder 00004092 0012101 ORD74348
53916	Backorder 00005070 0012101 ORD70778
55477	Backorder 00005439 0012101 ORD72007
56619	Backorder 00006245 0012101 ORD72608
66643	Backorder 00006666 0022192 ORD78204
54728	Backorder 00006673 0012101 ORD71532
56863	Backorder 00007020 0012101 ORD72795
60109	Backorder 00007020 0012101 ORD74861
62224	Backorder 00007025 0012105 ORD75814
59738	Backorder 00007246 0012101 ORD74612
62309	Backorder 00007246 0012101 ORD75884
64251	Backorder 00007246 0012101 ORD76878
67242	Backorder 00007246 0012101 ORD78589
54440	Backorder 00007356 0012101 ORD71324
59662	Backorder 00007356 0012101 ORD74570
62690	Backorder 00007374 0012103 ORD75999
53572	Backorder 00007410 0012105 ORD70850
54951	Backorder 00007410 0012105 ORD71696
60521	Backorder 00007410 0012105 ORD75012
66058	Backorder 00007410 0012105 ORD77919
53995	Backorder 00007586 0012101 ORD71005
54280	Backorder 00007586 0012101 ORD71202
55905	Backorder 00007586 0012101 ORD72256
58125	Backorder 00007586 0012101 ORD73615
58591	Backorder 00007586 0012101 ORD73926
59616	Backorder 00007586 0012101 ORD74528
61937	Backorder 00007586 0012101 ORD75647
66306	Backorder 00007586 0012101 ORD78047
66827	Backorder 00007586 0012101 ORD78366
56466	Backorder 00007688 0012101 ORD72522
67495	Backorder 00007786 0012101 ORD78717
69390	Backorder 00007786 0012106 ORD79539

Issue ID	Subject
65567	Backorder 00007995 0012101 ORD77595
54748	Backorder 00012340 0012101 ORD71554
57529	Backorder 00012340 0012101 ORD73291
60113	Backorder 00012340 0012101 ORD74868
53592	Backorder 00012340 0022190 ORD70883
56900	Backorder 00012340 0022190 ORD72841
60702	Backorder 00012340 0022190 ORD75132
54330	Backorder 00012340 0022191 ORD71235
56049	Backorder 00012340 0022191 ORD72372
59077	Backorder 00012489 0012101 ORD74215
60111	Backorder 00012904 0012101 ORD74862
65047	Beijing Choice Mini Booklet
50479	Drop tests: 0012101, 0012103, 0012105, 0012106
57769	Expected service Life: 0012101, 4410500, 4410520, 0012160, 4000 series Reuseable SPO2 sensors
51985	Finger Oximeters - R.H. Specification Update
55790	Finger Pulse Oximeters Feedback - MD300 - P/N: 2810011
67743	GHX - Unit of Measure
57401	GHX Brands
58392	GHX Export Template
67213	GHX Export Template: 0022193 info not exporting
46241	GHX/Peto exporter - image links
44817	Group Peto Group - Export
54413	Image exporter issues
48539	Low cost finger oximeters
52441	Marketing Schedule Low Cost Finger Oximeters PPQ
53369	Oximeter and sensor stock to order.
64547	Returned Items SOR652
16569	Sales projections 2009 - VM2101
16567	Sales projections 2009 - VM2101
16565	Sales projections VM2105
16563	Sales projections VM2105
55982	VM-2101, VM-2103, VM-2105: 0012101, 0012103, 0012105
55949	VM201, 2103 & 2105
65830	WYA Consignment Stock (349)
64946	WYA Consignment Stock (349)

Comments on Issues:

No problems identified in the issues system

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 stanrd piece of hospital equipment,
no recent clinic trials data found

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 fda reports found