



VIA MED

Pulse Oximeter VM-2160 AND SMA

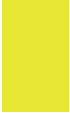
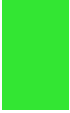
Handheld pulse oximeter for continuous and spot-check
monitoring of functional arterial oxygen saturation
(SpO₂) and pulse rate,

Class IIb
Via Rule 10
Assesment Route Annex II
NBOG MD1302

Carried out by Derek Lamb
20 / 04 / 16



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
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-  Design Changes Review
-  User Instructions Review
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-  Document Updates Review
-  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 SMARTsat.
0012166	Pulse Oximeter Viamed VM-2160 SMARTsat.
0012167	Pulse Oximeter Viamed VM 2160 SMARTsat.
0012168	Pulse Oximeter Viamed VM-2160 SMARTsat.
0012169	Pulse Oximeter Viamed VM-2160 SMARTsat.
0012170	Pulse Oximeter Viamed VM-2160 SMARTsat
0012171	Pulse Oximeter Viamed VM-2160 SMARTsat
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
0014651	SpO2 Finger Sensor - Adult.
0014752	SpO2 Silicone Finger Sensor - Adult.
0014753	SpO2 Silicone Finger Sensor - Paediatric
0014754	SpO2 Silicone Finger Sensor - Medium
0014850	Pulse Oximetry Ear Sensor
0014851	Pulse Oximetry Wrap Sensor
0014890	Sensor Wraps box of 12.
0014895	Pulse Oximetry Extension Cable 1.2 m
0014896	Pulse Oximetry Extension Cable 2.4 m
0015010	Disposable SpO2 Sensors - Adult.
0015011	Disposable SpO2 Sensors - Paediatric.
0015012	Disposable SpO2 Sensors - Infant.
0015013	Disposable SpO2 Sensors - Neonatal.
0022160	Protection cover - clear
0022178	Carrying case - for VM2160
0092171	Leaflet - VM 2160 Pulse Oximeter.

Comments on Stock references review:

part number upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0012155	Pulse Oximeter Viamed V	00009300		Bluepoint Medical	A
0012156	Pulse Oximeter Viamed V	00009300		Bluepoint Medical	A
0012157	Pulse Oximeter Viamed V	00009300		Bluepoint Medical	A
0012160	Pulse Oximeter Viamed V	00009300	1020112003	Bluepoint Medical	A
0012161	Pulse Oximeter Viamed V	00009300	1020112003 SCAND	Bluepoint Medical	A
0012162	Pulse Oximeter Viamed V	00009300	1020112003 EU SC	Bluepoint Medical	A
0012163	Pulse Oximeter Viamed V	00009300	1020112003 A I	Bluepoint Medical	A
0012164	Pulse Oximeter Viamed V	00009300	1020112003 A II	Bluepoint Medical	A
0012175	Pulse Oximeter Viamed V	00009300	4020112003	Bluepoint Medical	A
0012190	Pulse Oximeter Viamed V	00009300		Bluepoint Medical	A
0014651	SpO2 Finger Sensor - Adu	00009300		Bluepoint Medical	A
0014752	SpO2 Silicone Finger Sen	00009300		Bluepoint Medical	A
0014753	SpO2 Silicone Finger Sen	00009300		Bluepoint Medical	A
0014754	SpO2 Silicone Finger Sen	00009300		Bluepoint Medical	A
0014850	Pulse Oximetry Ear Senso	00009300		Bluepoint Medical	A
0014851	Pulse Oximetry Wrap Sens	00009300		Bluepoint Medical	A
0014890	Sensor Wraps box of 12.	00009300	6020621001	Bluepoint Medical	A
0014895	Pulse Oximetry Extension	00009300	1020132288	Bluepoint Medical	A
0014896	Pulse Oximetry Extension	00009300	1020132296	Bluepoint Medical	A
0015010	Disposable SpO2 Sensors	00009300		Bluepoint Medical	A
0015011	Disposable SpO2 Sensors	00009300		Bluepoint Medical	A
0015012	Disposable SpO2 Sensors	00009300		Bluepoint Medical	A
0015013	Disposable SpO2 Sensors	00009300		Bluepoint Medical	A
0022160	Protection cover - clear	00009300	1020122056	Bluepoint Medical	A
0092171	Leaflet - VM 2160 Pulse	00009345		Duffield Printers	A
0092171	Leaflet - VM 2160 Pulse	00009360		Print Centre	B
0092171	Leaflet - VM 2160 Pulse	00009366		Warwick Printing	B
0022178	Carrying case - for VM21	00009445	POU0092	Openhouse Products Ltd	B

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0012155	Pulse Oximeter Viamed V	5	24	7				
0012156	Pulse Oximeter Viamed V							
0012157	Pulse Oximeter Viamed V							
0012158	Pulse Oximeter Viamed VM 2160-L.							
0012159	Pulse Oximeter Viamed VM 2160-L.							
0012160	Pulse Oximeter Viamed V	299	226	190	322	276	109	44
0012161	Pulse Oximeter Viamed V	63	197	175	254	166	144	50
0012162	Pulse Oximeter Viamed V	31	30	23	35	32	16	90
0012163	Pulse Oximeter Viamed V	8						
0012164	Pulse Oximeter Viamed V	2						
0012165	Pulse Oximeter Viamed VM-2160 SMARTsat.							
0012166	Pulse Oximeter Viamed VM-2160 SMARTsat.							
0012167	Pulse Oximeter Viamed VM 2160 SMARTsat.							
0012168	Pulse Oximeter Viamed VM-2160 SMARTsat.							
0012169	Pulse Oximeter Viamed VM-2160 SMARTsat.							
0012170	Pulse Oximeter Viamed VM-2160 SMARTsat							
0012171	Pulse Oximeter Viamed VM-2160 SMARTsat							
0012175	Pulse Oximeter Viamed V		32	43	52	39	26	9
0012176	Pulse Oximeter Viamed VM 2160.						2	3
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 V	1						
0014651	SpO2 Finger Sensor - Adu							
0014752	SpO2 Silicone Finger Sen							
0014753	SpO2 Silicone Finger Sen							
0014754	SpO2 Silicone Finger Sen							
0014850	Pulse Oximetry Ear Senso							
0014851	Pulse Oximetry Wrap Sens							
0014890	Sensor Wraps box of 12.				2		26	
0014895	Pulse Oximetry Extension	11	18	26	35	36	18	91
0014896	Pulse Oximetry Extension	6	4	3	3			
0015010	Disposable SpO2 Sensors							
0015011	Disposable SpO2 Sensors							
0015012	Disposable SpO2 Sensors							
0015013	Disposable SpO2 Sensors							
0022160	Protection cover - clear	5	5				1	
0022178	Carrying case - for VM21			100	51	1	1	
0092171	Leaflet - VM 2160 Pulse	50	30	120	80	45	10	

Comments on Sales Information:

units still selling

Countries Review

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

Country	2010	2011	2012	2013	2014	2015	2016
SY Syria	[X]						
T Turkey	[X]	[X]	[X]	[X]		[X]	
TH Thailand			[X]	[X]			
TUN Tunisia							
UAE U A E	[X]	[X]	[X]	[X]	[X]	[X]	
UG UGANDA				[X]			
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
VI Vietnam		[X]	[X]	[X]	[X]		

Comments on Sales to Countries:

LI Lithuania, PE Peru, SL Slovenia
are new countries

Comments on Risks with Sales to Countries:

no risks identified with new countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0012155	Display fault					1		
0012155	Error message: Device defective							
0012155	Keypad fault		3					
0012155	No Fault Found		1	2				
0012155	OLED display faded						3	
0012155	OLED display replaced						1	3
0012160	Case fault			2				
0012160	Case refitted	1						
0012160	Chipox reseated						1	
0012160	Customer Declined Quotation	1						
0012160	Data transfer error							
0012160	Dead	1	1	2	1			
0012160	Display - missing pixels							
0012160	Display - speck of dust							
0012160	Display fault	8	15	9	10	3	1	
0012160	Error message: Device defective	1						
0012160	Fault code: Sensor fault				1	2		
0012160	Faulty probe							
0012160	Firmware flashed						1	1
0012160	Intermittent			1				
0012160	Keypad fault	7	3	1				
0012160	Membrane replaced	2						
0012160	No Fault Found	4		2				
0012160	No Fault Return to Stock	2						
0012160	OLED display faded					9	1	
0012160	OLED display replaced						12	9
0012160	On/off button fault		6	1				
0012160	On/Off button intermittent	1						
0012160	PCB damaged							1
0012160	PCB reseated			2		1		
0012160	QA carried out							
0012160	Quote not accepted			2	1			
0012160	Reprogrammed			1		1		
0012160	TEST	1						
0012160	Unchecked - Returned to Stock							
0012160	Upgraded			6				
0012161	Causes error message			1				
0012161	Dead					1		
0012161	Device Defective						1	
0012161	Display fault		1			1		
0012161	Error message: Device defective	1						
0012161	Fault code: Sensor fault						1	

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0012161	Intermittent			1				
0012161	Keypad fault		1			1		
0012161	No Fault Found		2	2	4			
0012161	OLED display faded					2	3	
0012161	OLED display replaced						2	1
0012161	On/off button fault		1					
0012161	On/Off button intermittent							
0012161	Unable to switch on					1		
0012161	Upgraded			1				
0012162	Chipox not recognised							1
0012162	Display fault	1	1	1				
0012162	Keypad fault	1						
0012162	No Fault Found							
0012162	OLED display faded							
0012162	OLED display replaced						1	6
0012162	On/Off button intermittent							
0012162	QA carried out	13						
0012162	Upgraded			2				
0012163	Display fault		1					
0012163	QA carried out	1						
0012164	QA carried out	3						
0012175	Battery contacts corroded					1		1
0012175	Dead					1		
0012175	Device Defective				1	2		
0012175	Display fault						1	
0012175	Firmware error						1	
0012175	No Fault Return to Stock				1			
0012175	OLED display faded					1	2	1
0012175	OLED display replaced						7	3
0012175	PCB damaged					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:

low return rate - mainly oled display faults - getting dimmer

Comments on Risks with Returns and Potential Re-work:

no risk identified with returns,
with regard the oled, they still work just the brightness got lower

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
15506	Pulse Oximeter VM-2160 Quick Start Guide	24/08/15
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:

added a quick start guide in addition to the full IFU

Comments on Risks User Instructions:

no risks identified with IFUs

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
14922	Pulse Oximeter VM-2160 Labels Back Case	13/04/15
14921	Pulse Oximeter VM-2160 Labels Outer Box	13/04/15
9169	No accessory labels	18/10/11
3950	Pulse Oximeter VM-2160 Labels Outer box main Label	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

Comments on Labels:

Blue man symbol added to the labeling

Comments on Risks Labels:

no risks identified with the new labeling

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16499	VM2160 Declaration of Electromagnetic Emissions IEC 60601-1-2:20...	17/03/16
16405	Pulse Oximeter VM-2160 AND SMARTsat SpO2 AND sensors Design Inpu...	01/03/16
16257	Pulse Oximeter VM-2160 AND SMARTsat SpO2 AND sensors Literature ...	08/02/16
16021	0012160 Pulse Oximeter VM-2160 Viamed Leaflets (print) (email)	19/11/15
15837	Pulse Oximeter VM-2160 General Certificates Certificate of Free ...	19/10/15
15506	Pulse Oximeter VM-2160 Quick Start Guide	24/08/15
15418	PPE Equipment	11/08/15
15009	Competitor Product MHRA FDA Field Safety Notices Covidien Displa...	26/05/15
14922	Pulse Oximeter VM-2160 Labels Back Case	13/04/15
14921	Pulse Oximeter VM-2160 Labels Outer Box	13/04/15
14920	Pulse Oximeter VM-2160 OES (OEM) Labels for OBLs	13/04/15
14886	Capnograph Expected Life of Products Various Products Blue poin...	27/03/15
14879	Pulse Oximeter VM2160 VET OLED Version	26/03/15
14878	Pulse Oximeter VM2160 Asia 2 OLED Version	26/03/15
14877	Pulse Oximeter VM-2160 Software VM2160 Asia 1 OLED Version	26/03/15
14876	Pulse Oximeter VM-2160 Software VM2160 Special European Characte...	26/03/15
14875	Pulse Oximeter VM-2160 Software VM2160 Special Europe (Scandinav...	26/03/15
14874	Pulse Oximeter VM-2160 Software VM2160 Central Europe OLED Versi...	26/03/15
14873	Pulse Oximeter VM-2160 Software Explanation of Versions and Lan...	26/03/15
14872	Pulse Oximeter VM-2160 Software Demo Firmware V2.7 VM2160 Firmwa...	26/03/15
14871	Pulse Oximeter VM-2160 Software Special European Characters V2.7...	26/03/15
14870	Pulse Oximeter VM-2160 Software North Europe (Scandinavian) V2.7...	26/03/15
14869	Pulse Oximeter VM-2160 Software Central Europe V2.7 VM2160 Firmw...	26/03/15
14868	Pulse Oximeter VM-2160 Software Asia 12 V2.7 VM2160 Firmware TF...	26/03/15
14867	Pulse Oximeter VM-2160 Software Asia 1, V2.7 VM2160 Firmware TF...	26/03/15
14811	Pulse Oximeter VM-2160 Promotional Leaflets VM-2160 Leaflet in F...	26/02/15
14810	Pulse Oximeter VM-2160 Promotional Leaflets VM-2160 Leaflet in F...	26/02/15
14809	Pulse Oximeter VM-2160 Promotional Leaflets VM-2160 Leaflet in F...	26/02/15
14602	BPM Annex II BPM Notified body certification Blue Point EC Certi...	10/12/14
14275	Pulse Oximeter VM-2160 Clinical Trials Reports Reviews and Post ...	16/09/14

Comments on Document Changes:

firmware updates, some extra files from the oem.

Comments on Risks with Document Changes:

no risks identified with new documentation

Internal Issues Review

Number of Issues reviewed: 135

Issue ID	Subject
12304	
12302	
12301	
61505	0012160 - Free carriage
61504	0012160 - Free carriage
14145	0012160 100 off price
57854	0014890 - Viamed Wrap advert
58133	0014890 Sensor Wrap Card Advert
17013	7 x 0012162 from POR06003
15651	Any feedback from the customer?
15650	Any feedback from the demo?
64211	Backorder 00000970 0012160 ORD76865
53859	Backorder 00006107 0012160 ORD70948
57278	Backorder 00006254 0092171 ORD73026
60534	Backorder 00006280 0012175 ORD75027
68483	Backorder 00006297 0012160 ORD79055
65169	Backorder 00006308 0012176 ORD77302
65492	Backorder 00006308 0012176 ORD77547
66315	Backorder 00006308 0012176 ORD78036
67193	Backorder 00006308 0012176 ORD78564
65565	Backorder 00006317 0012160 ORD77592
68535	Backorder 00006317 0012160 ORD79179
62411	Backorder 00007020 0012160 ORD75920
66130	Backorder 00007020 0012160 ORD77976
54279	Backorder 00007025 0012160 ORD71158
64772	Backorder 00007025 0012160 ORD77104
69996	Backorder 00007025 0012160 ORD79755
57740	Backorder 00007246 0012160 ORD73369
61133	Backorder 00007246 0012160 ORD75273
62623	Backorder 00007327 0012161 ORD75997
54618	Backorder 00007415 0012160 ORD71451
55124	Backorder 00007515 0012161 ORD71777
55837	Backorder 00007515 0012161 ORD72209
58422	Backorder 00007515 0012161 ORD73818
60292	Backorder 00007515 0012161 ORD74918
64510	Backorder 00007515 0012161 ORD76996
66531	Backorder 00007515 0012161 ORD78156
66745	Backorder 00007515 0012161 ORD78273
67771	Backorder 00007515 0012161 ORD78839
53593	Backorder 00007542 0012160 ORD70885
64489	Backorder 00007542 0012160 ORD76938
54790	Backorder 00007688 0012160 ORD71545

Issue ID	Subject
58605	Backorder 00007799 0012162 ORD73847
54620	Backorder 00007881 0012160 ORD71455
65721	Backorder 00007881 0012160 ORD77694
65722	Backorder 00007881 0012160 ORD77695
64002	Backorder 00007995 0012162 ORD76754
66552	Backorder 00007995 0012162 ORD78159
66823	Backorder 00007995 0012162 ORD78167
68719	Backorder 00007995 0012162 ORD78169
68462	Backorder 00011982 0012160 ORD79034
54282	Backorder 00011982 0012175 ORD71204
60527	Backorder 00011982 0012175 ORD75022
64632	Backorder 00011982 0012175 ORD77043
68463	Backorder 00011982 0012175 ORD79034
69074	Backorder 00012163 2510000 ORD79348
54599	Backorder 00012178 0110015 ORD71435
55942	Backorder 00012178 0110015 ORD72297
61944	Backorder 00012178 0110017 ORD75651
63517	Backorder 00012178 0110017 ORD76428
54886	Backorder 00012178 0110022 ORD71613
57177	Backorder 00012178 0110040 ORD73042
59252	Backorder 00012178 0110040 ORD74296
53641	Backorder 00012178 0110425 ORD70904
57094	Backorder 00012178 0110425 ORD72972
57928	Backorder 00012178 0110425 ORD73487
58705	Backorder 00012178 0110425 ORD74004
59410	Backorder 00012178 0110425 ORD74411
63721	Backorder 00012178 0110425 ORD76565
64213	Backorder 00012178 0110425 ORD76868
67544	Backorder 00012178 0110425 ORD78744
69471	Backorder 00012178 0110425 ORD79570
65806	Backorder 00012178 1410000 ORD77767
54743	Backorder 00012178 2510000 ORD71542
56024	Backorder 00012178 2510000 ORD72351
65974	Backorder 00012178 2510000 ORD77892
55133	Backorder 00012178 2520000 ORD71756
66753	Backorder 00012369 0012160 ORD78287
54749	Backorder 00012456 0012160 ORD71555
54779	Backorder 00012742 0012160 ORD71571
54885	Backorder 00012880 0012160 ORD71609
57429	Contact Details Update
57209	Contact Details Update
57284	Crown Agents updates
57769	Expected service Life: 0012101, 4410500, 4410520, 0012160, 4000 series Reuseable SPO2 sensors
53284	Further documentation required for VM-2500 Taiwan Registration
50739	Further testing information - MAX250(B) on SRS64344

Issue ID	Subject
54413	Image exporter issues
58150	Leaflet 0014890 Sensor Wrap Card Advert 2nd Checking Stage
58198	Leaflet 0014890 Sensor Wrap Card Advert 3rd Checking Stage
58325	Leaflet 0014890 Sensor Wrap Card Advert PDFs generated for L
63017	Lost Customers Tag in Sales
16032	Needs to be booked out to Ryan
58617	NHS Shared Business Services monthly report
63593	Out of date VM-2160 leaflet
53369	Oximeter and sensor stock to order.
55874	Pallet - Weight and Dimensions... JSC order
16033	Please remove from SOR156
15307	Please scan to demo stock.
70175	POR10652 0015010 //
70176	POR10652 0015011 //
70179	POR10652 0015012 //
70178	POR10652 0015013 //
70177	POR10652 0015013 //
57732	QA form, obsolete questions
16072	Replacement to be sent under warranty
13590	Requested part numbers
15273	Return to Keith?
53338	Returned Items SOR621
64547	Returned Items SOR652
64264	Returned Items SOR655
16573	Sales projections 2009 - VM2160
16571	Sales projections 2009 - VM2160
16081	Status pull down list edits
64982	Stock Accessories - Pen Icon
58135	Viamed 0014890 Sensor Wrap
64113	Viamed SMARTsat SpO2 sensors
64112	Viamed SMARTsat SpO2 sensors
54763	Viamed VM-2160 Feedback from Morning Star Medical Equipment
15131	VM 2160 - To be returned to Keith or for demo stock?
14572	VM 2160 variants and Opera numbers
14571	VM 2160 variants and Opera numbers
14570	VM 2160 variants and Opera numbers
14568	VM 2160 variants and Opera numbers
14567	VM 2160 variants and Opera numbers
14566	VM 2160 variants and Opera numbers
54900	VM-2160 0012160
56168	VM-2160 0012160 Leaflet in French
62039	VM-2160 Quick Start Guide V2.0
63735	VM-2160 SmartSat Leaflet
64029	VM-2160 SMARTsat leaflet
14550	Vm2160 sales projections

Issue ID	Subject
14549	Vm2160 sales projections
58141	Web Site Question ID 442
65069	Web Site Question ID 749

Comments on Issues:

normal issues orders / stocking trials.

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 :

Held with the OEM,
Pulse Oximetry standard equipment,
still in use.

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 :

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm341718.htm>
no reports found but a guidance document turned up,
with some recommendations on reprocessing of the sensors.
no risks identified