



VIA MED

Capnograph

Hand held capnograph and pulse oximeter for continuous and spot-check monitoring of end-tidal CO₂ concentration (EtCO₂), inspired CO₂ concentration (FiCO₂), functional arterial oxygen saturation (SpO₂) respiration rate and pulse rate.

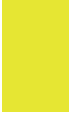
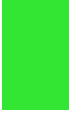
Class IIb

Assesment Route Annex II
NBOG MD 1302

Carried out by Derek Lamb
18 / 05 / 15



VIA MED

-  Stock References Review
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Stock References Review

Stock Reference	Description
4410500	Capnograph VM-2500-M
4410501	Capnograph VM-2500-M
4410520	Capnograph VM-2500-S
4410521	Capnograph VM-2500-S
4410530	Capnograph VM-2500-M Veterinary version
4410540	Capnograph VM-2500-S Veterinary version
4410550	Multigas VM-2500-MG
4410560	Multigas VM-2500-MG Veterinary version
4420504	ISA CO2 analyzer
4420505	IRMA CO2 analyzer
4420506	IRMA AX+ analyzer for use with Multi-Gas
4420510	IRMA airway adapter - adult/paediatric
4420511	IRMA airway adapter - adult/paediatric
4420512	IRMA airway adapter - adult/paediatric
4420520	IRMA airway adapter - infant
4420521	IRMA airway adapter - infant
4420522	IRMA airway adapter - infant adapter.
4420525	Nomo adapter for use with VM-2500-S
4420527	Nomoline PhaseIn.
4420528	Nomoline PhaseIn. Box of 25
4420529	Nomoline for use with VM-2500-S.
4420530	Nomoline for use with VM-2500-S. Box 25
4420531	Sidestream disposable airway adapter
4420532	Sidestream disposable airway adapter
4420541	Sidestream disposable airway adapter
4420542	Sidestream disposable airway adapter
4420545	Autoclavable sidestream airway adapter
4420550	Disposable sampling line. Box of 25.
4420551	Disposable sampling line.
4420552	Disposable airway adapter sampling line.
4420553	Disposable airway adapter sampling line.
4420560	Disposable nasal sampling line.Box of 40
4420561	Disposable nasal sampling line.
4420570	15mm adapters I.D. 2.0 mm. Box of 10
4420571	15mm adapters I.D. 2.5 mm. Box of 10
4420572	15mm adapters I.D. 3.0 mm. Box of 10
4420573	15mm adapters I.D. 3.5 mm. Box of 10
4420574	15mm adapters I.D. 4.0 mm. Box of 10
4420575	15mm adapters I.D. 5.0 mm. Box of 10
4420576	15mm adapters I.D. 6.0 mm. Box of 10
4420577	15mm adapters I.D. 7.0 mm. Box of 10
4420578	15mm adapters I.D. 8.0 mm. Box of 10

Stock Reference	Description
4420579	15mm adapters I.D. 9.0 mm. Box of 10
4420580	15mm adapters I.D. 10.0 mm. Box of 10
4420590	Rechargeable Li-Poly battery CT-2500 for
4420594	Power supply for use with
4420595	Power supply for use with
4420596	Power supply for use with
4420597	USB cable for use with Viamed
4420600	Universal mounting kit Rev. 1 - for use
4420601	Universal mounting kit Rev. 2 - for use
4420610	Silicone cover - for use with
4420611	Silicone cover - for use with
4420612	Silicone cover kit - for use with IRMA
4420613	IRMA Holder
4420614	ISA Medirail Holder
4420615	Protective Rubber Boot - for use with
4420616	IRMA Medirail Holder
4420618	Clamp Adapter
4420620	Carrying case - for use with
4420621	Carrying case with clear panel for use
4420628	Carrying case (A&E logo) - for use with
4420630	Carrying case - custom version.
4420670	15mm adapter I.D. 2.0 mm.
4420671	15mm adapter I.D. 2.5 mm.
4420672	15mm adapter I.D. 3.0 mm.
4420673	15mm adapter I.D. 3.5 mm.
4420674	15mm adapter I.D. 4.0 mm.
4420675	15mm adapter I.D. 5.0 mm.
4420676	15mm adapter I.D. 6.0 mm.
4420677	15mm adapter I.D. 7.0 mm.
4420678	15mm adapter I.D. 8.0 mm.
4420679	15mm adapter I.D. 9.0 mm.
4420680	15mm adapter I.D. 10.0 mm.
4420710	CO2 Nasal Sampling Cannula - Adult.
4420711	CO2 Nasal Sampling Cannula - Paediatric.
4420712	CO2 Nasal Sampling Cannula -
4420713	CO2 Nasal Sampling Cannula - Infant
4420718	CO2 Nasal Sampling Cannula with O2 -
4420719	CO2 Nasal Sampling Cannula with O2 -
4420720	CO2 Nasal Sampling Cannula with O2 -
4420721	CO2 Nasal Sampling Cannula with O2 -
4420730	CO2 Nasal/Oral Sampling Cannula
4420731	CO2 Nasal/Oral Sampling Cannula
4420738	CO2 Nasal/Oral Sampling Cannula with O2
4420739	CO2 Nasal/Oral Sampling Cannula with O2
4420740	CO2 Nasal/Oral Sampling Cannula with O2

Stock Reference	Description
4420741	CO2 Nasal/Oral Sampling Cannula with O2
4420760	CO2 Nasal Sampling Cannula - Adult.
4420761	CO2 Nasal Sampling Cannula - Paediatric.
4420762	CO2 Nasal Sampling Cannula -
4420763	CO2 Nasal Sampling Cannula - Infant
4420770	CO2 Nasal Sampling Cannula with O2 -
4420771	CO2 Nasal Sampling Cannula with O2 -
4420780	CO2 Nasal/Oral Sampling Cannula
4420781	CO2 Nasal/Oral Sampling Cannula
4420790	CO2 Nasal/Oral Sampling Cannula with O2
4420791	CO2 Nasal/Oral Sampling Cannula with O2
4440000	Labour - VM-2500 Capnograph
4480500	Calibration check - Capnograph VM-2500-M
4480520	Calibration check - Capnograph VM-2500-S
4490095	Leaflet - VM 2500 Capnograph Accessories

Comments on Stock references review:

added calibration checks and leaflets

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
4420560	Disposable nasal samplin	00009299	5090121001-40	Bluepoint Medical	A
4410500	Capnograph VM-2500-M	00009300	3090112005	Bluepoint Medical	A
4410501	Capnograph VM-2500-M	00009300		Bluepoint Medical	A
4410520	Capnograph VM-2500-S	00009300	3090112007	Bluepoint Medical	A
4410530	Capnograph VM-2500-M Ve	00009300	4090112010	Bluepoint Medical	A
4410540	Capnograph VM-2500-S Ve	00009300	4090112011	Bluepoint Medical	A
4410550	Multigas VM-2500-MG	00009300	5090112001	Bluepoint Medical	A
4410560	Multigas VM-2500-MG Vet	00009300	6090112001	Bluepoint Medical	A
4420505	IRMA CO2 analyzer	00009300		Bluepoint Medical	A
4420510	IRMA airway adapter - ad	00009300	305121001	Bluepoint Medical	A
4420511	IRMA airway adapter - ad	00009300		Bluepoint Medical	A
4420520	IRMA airway adapter - in	00009300	3050121002	Bluepoint Medical	A
4420521	IRMA airway adapter - in	00009300		Bluepoint Medical	A
4420525	Nomo adapter for use wit	00009300	4090122003	Bluepoint Medical	A
4420527	Nomoline PhaseIn.	00009300		Bluepoint Medical	A
4420528	Nomoline PhaseIn. Box o	00009300		Bluepoint Medical	A
4420531	Sidestream disposable ai	00009300		Bluepoint Medical	A
4420550	Disposable sampling line	00009300		Bluepoint Medical	A
4420590	Rechargeable Li-Poly bat	00009300		Bluepoint Medical	A
4420594	Power supply for use wit	00009300	6090122003	Bluepoint Medical	A
4420595	Power supply for use wit	00009300	3090122002	Bluepoint Medical	A
4420600	Universal mounting kit	00009300	3090122008	Bluepoint Medical	A
4420601	Universal mounting kit	00009300	4090122001	Bluepoint Medical	A
4420610	Silicone cover - for use	00009300	3090122006	Bluepoint Medical	A
4420611	Silicone cover - for use	00009300	6090122004	Bluepoint Medical	A
4420615	Protective Rubber Boot -	00009300	609122002	Bluepoint Medical	A
4420710	CO2 Nasal Sampling Cannu	00009300	5090121004-25	Bluepoint Medical	A
4420711	CO2 Nasal Sampling Cannu	00009300	5090121002-25	Bluepoint Medical	A
4420713	CO2 Nasal Sampling Cannu	00009300	5090121005	Bluepoint Medical	A
4420718	CO2 Nasal Sampling Cannu	00009300	5090121006	Bluepoint Medical	A
4420719	CO2 Nasal Sampling Cannu	00009300	5090121007	Bluepoint Medical	A
4420730	CO2 Nasal/Oral Sampling	00009300	5090121008-25	Bluepoint Medical	A
4420731	CO2 Nasal/Oral Sampling	00009300	5090121009-25	Bluepoint Medical	A
4420738	CO2 Nasal/Oral Sampling	00009300	5090121010	Bluepoint Medical	A
4420739	CO2 Nasal/Oral Sampling	00009300	5090121011	Bluepoint Medical	A
4420528	Nomoline PhaseIn. Box o	00009330		Saadat (M) Snd Bhd (EURO	B
4420613	IRMA Holder	00009330	0000-6560/04	Saadat (M) Snd Bhd (EURO	B
4420614	ISA Medirail Holder	00009330	0000-8179/00	Saadat (M) Snd Bhd (EURO	B
4420618	Clamp Adapter	00009330	P20063	Saadat (M) Snd Bhd (EURO	B
4420570	15mm adapters I.D. 2.0	00009334	44-3500-020-1	VBM Medizintechnik GmbH	B
4420571	15mm adapters I.D. 2.5	00009334	44-3500-025-1	VBM Medizintechnik GmbH	B
4420572	15mm adapters I.D. 3.0	00009334	44-3500-030-1	VBM Medizintechnik GmbH	B

Stock Reference	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
4420573	15mm adapters I.D. 3.5	00009334	44-3500-035-1	VBM Medizintechnik GmbH	B
4420574	15mm adapters I.D. 4.0	00009334	44-3500-040-1	VBM Medizintechnik GmbH	B
4420575	15mm adapters I.D. 5.0	00009334	44-3500-050-1	VBM Medizintechnik GmbH	B
4420576	15mm adapters I.D. 6.0	00009334	44-3500-060-1	VBM Medizintechnik GmbH	B
4420577	15mm adapters I.D. 7.0	00009334	44-3500-070-1	VBM Medizintechnik GmbH	B
4420578	15mm adapters I.D. 8.0	00009334	44-3500-080-1	VBM Medizintechnik GmbH	B
4420579	15mm adapters I.D. 9.0	00009334	44-3500-090-1	VBM Medizintechnik GmbH	B
4420580	15mm adapters I.D. 10.0	00009334	44-3500-100-1	VBM Medizintechnik GmbH	B
4490095	Leaflet - VM 2500 Capnog	00009366		Warwick Printing	B
4420620	Carrying case - for use	00009445	POU0096	Openhouse Products Ltd	B
4420621	Carrying case with clear	00009445	POU0190FOR-GB	Openhouse Products Ltd	B
4420628	Carrying case (A&E logo)	00009445		Openhouse Products Ltd	B

Comments on Suppliers:

Certificates still in date,
no problems with suppliers

Sales Information

Stock Reference	Description	2009	2010	2011	2012	2013	2014	2015
4410500	Capnograph VM-2500-M		19	17	34	41	27	2
4410501	Capnograph VM-2500-M				2			
4410520	Capnograph VM-2500-S		76	62	51	65	90	13
4410521	Capnograph VM-2500-S							
4410530	Capnograph VM-2500-M Ve			8	10	4	20	10
4410540	Capnograph VM-2500-S Ve			1	3	22	24	6
4410550	Multigas VM-2500-MG				3	3		
4410560	Multigas VM-2500-MG Vet					2		
4420504	ISA CO2 analyzer					1		
4420505	IRMA CO2 analyzer				5	3	4	
4420506	IRMA AX+ analyzer for use with Multi-Gas					2	2	1
4420510	IRMA airway adapter - ad							
4420511	IRMA airway adapter - ad		13	8	31	59	63	7
4420512	IRMA airway adapter - adult/paediatric			3	7		5	
4420520	IRMA airway adapter - in							
4420521	IRMA airway adapter - in		12	4	16	4	39	11
4420522	IRMA airway adapter - infant adapter.		2		2			
4420525	Nomo adapter for use wit		91	31	101	237	443	81
4420527	Nomoline PhaseIn.		8					
4420528	Nomoline PhaseIn. Box o			1	7	12	17	3
4420529	Nomoline for use with VM-2500-S.							
4420530	Nomoline for use with VM-2500-S. Box 25							
4420531	Sidestream disposable ai		16	22	36	35	57	13
4420532	Sidestream disposable airway adapter			6		2	2	
4420541	Sidestream disposable airway adapter							
4420542	Sidestream disposable airway adapter							
4420545	Autoclavable sidestream airway adapter							
4420550	Disposable sampling line		21	26	32	27	78	18
4420551	Disposable sampling line.			5	1	2	2	
4420552	Disposable airway adapter sampling line.							
4420553	Disposable airway adapter sampling line.							
4420560	Disposable nasal samplin			3	11	2	4	
4420561	Disposable nasal sampling line.			8	5	2	2	
4420570	15mm adapters I.D. 2.0					1	15	1
4420571	15mm adapters I.D. 2.5				10	1	1	1
4420572	15mm adapters I.D. 3.0				1	1	1	1
4420573	15mm adapters I.D. 3.5					1	1	1
4420574	15mm adapters I.D. 4.0							
4420575	15mm adapters I.D. 5.0							
4420576	15mm adapters I.D. 6.0							
4420577	15mm adapters I.D. 7.0							
4420578	15mm adapters I.D. 8.0							

Stock Reference	Description	2009	2010	2011	2012	2013	2014	2015
4420579	15mm adapters I.D. 9.0							
4420580	15mm adapters I.D. 10.0		2				1	
4420590	Rechargeable Li-Poly bat				4	7	1	4
4420594	Power supply for use wit					3		3
4420595	Power supply for use wit		2	3	9	10	19	7
4420596	Power supply for use with							
4420597	USB cable for use with Viamed				1			
4420600	Universal mounting kit		9	4		1		
4420601	Universal mounting kit				6	9	41	1
4420610	Silicone cover - for use				1			
4420611	Silicone cover - for use							1
4420612	Silicone cover kit - for use with IRMA					4		
4420613	IRMA Holder					200		160
4420614	ISA Medirail Holder					1250	4	500
4420615	Protective Rubber Boot -						5	6
4420616	IRMA Medirail Holder							
4420618	Clamp Adapter					600		
4420620	Carrying case - for use		22	11	49	15	4	3
4420621	Carrying case with clear					2	6	1
4420628	Carrying case (A&E logo)					4		
4420630	Carrying case - custom version.		8					
4420670	15mm adapter I.D. 2.0 mm.		2				2	
4420671	15mm adapter I.D. 2.5 mm.		2				2	
4420672	15mm adapter I.D. 3.0 mm.		2				2	
4420673	15mm adapter I.D. 3.5 mm.		2				1	
4420674	15mm adapter I.D. 4.0 mm.		2				3	
4420675	15mm adapter I.D. 5.0 mm.		2				2	
4420676	15mm adapter I.D. 6.0 mm.		2				3	
4420677	15mm adapter I.D. 7.0 mm.		2				1	
4420678	15mm adapter I.D. 8.0 mm.		2					
4420679	15mm adapter I.D. 9.0 mm.		2					
4420680	15mm adapter I.D. 10.0 mm.		2					
4420710	CO2 Nasal Sampling Cannu			4		3	10	
4420711	CO2 Nasal Sampling Cannu					2	5	4
4420712	CO2 Nasal Sampling Cannula -							
4420713	CO2 Nasal Sampling Cannu					1	4	1
4420718	CO2 Nasal Sampling Cannu				1	9	41	
4420719	CO2 Nasal Sampling Cannu				1	2	11	
4420720	CO2 Nasal Sampling Cannula with O2 -							
4420721	CO2 Nasal Sampling Cannula with O2 -							
4420730	CO2 Nasal/Oral Sampling			2	10	10	9	
4420731	CO2 Nasal/Oral Sampling			2	4	1	8	
4420738	CO2 Nasal/Oral Sampling				1	17	26	1
4420739	CO2 Nasal/Oral Sampling				1	5	20	1
4420740	CO2 Nasal/Oral Sampling Cannula with O2							

Stock Reference	Description	2009	2010	2011	2012	2013	2014	2015
4420741	CO2 Nasal/Oral Sampling Cannula with O2							
4420760	CO2 Nasal Sampling Cannula - Adult.					8	2	
4420761	CO2 Nasal Sampling Cannula - Paediatric.					6		
4420762	CO2 Nasal Sampling Cannula -							
4420763	CO2 Nasal Sampling Cannula - Infant							
4420770	CO2 Nasal Sampling Cannula with O2 -					9	2	
4420771	CO2 Nasal Sampling Cannula with O2 -					3		
4420780	CO2 Nasal/Oral Sampling Cannula			22	12	2	5	
4420781	CO2 Nasal/Oral Sampling Cannula			9	10	6		
4420790	CO2 Nasal/Oral Sampling Cannula with O2						2	
4420791	CO2 Nasal/Oral Sampling Cannula with O2							
4440000	Labour - VM-2500 Capnograph							
4480500	Calibration check - Capnograph VM-2500-M							
4480520	Calibration check - Capnograph VM-2500-S							
4490095	Leaflet - VM 2500 Capnog							

Comments on Sales Information:

Sales appear to have dropped in 2015.
units/consumables are still selling.

Countries Review

Country	2009	2010	2011	2012	2013	2014	2015
B Belgium		[X]	[X]	[X]	[X]	[X]	[X]
BA State of Bahrain					[X]		
C China					[X]	[X]	[X]
CAN Canada					[X]	[X]	[X]
CRO Croatia			[X]				
CZ Czech Republic		[X]					
DE Denmark		[X]			[X]		
ES Estonia					[X]	[X]	
F France		[X]			[X]	[X]	
FI Finland		[X]	[X]	[X]	[X]	[X]	[X]
G Germany		[X]	[X]	[X]	[X]	[X]	
GR Greece		[X]					
HK Hong Kong				[X]	[X]		
I Iran		[X]	[X]				
IN India			[X]				[X]
IND Indonesia					[X]		
IQ IRAQ					[X]	[X]	
IRE Ireland			[X]	[X]	[X]	[X]	[X]
IS Israel		[X]				[X]	[X]
KU Kuwait			[X]			[X]	
LEB Lebanon		[X]		[X]			
MA Malaysia		[X]	[X]	[X]			[X]
MAU Mauritius					[X]		
MEX Mexico						[X]	
NE Netherlands		[X]		[X]		[X]	
NO Norway		[X]	[X]	[X]	[X]	[X]	
NZ New Zealand					[X]		[X]
OM Oman		[X]			[X]	[X]	[X]
PO Portugal						[X]	
RO Romania					[X]		
RU Russia					[X]		[X]
SA South Africa			[X]	[X]			
SAU Saudi Arabia		[X]	[X]	[X]	[X]	[X]	
SL Slovenia					[X]	[X]	
SP Spain		[X]		[X]	[X]	[X]	[X]
SRI Sri Lanka				[X]			
SW Sweden		[X]	[X]	[X]	[X]	[X]	[X]
SWI Switzerland						[X]	
SY Syria		[X]	[X]				
T Turkey		[X]	[X]	[X]	[X]	[X]	
TH Thailand			[X]	[X]	[X]	[X]	
UAE U A E				[X]	[X]	[X]	

Country	2009	2010	2011	2012	2013	2014	2015
UK United Kingdom		[X]	[X]	[X]	[X]	[X]	[X]
VI Vietnam				[X]	[X]		[X]

Comments on Sales to Countries:

New country Switzerland,

Comments on Risks with Sales to Countries:

no risks identified with new countries

Returns Review

Stock Reference	Fault	2009	2010	2011	2012	2013	2014	2015
4410500	CO2 probe not detected		1					
4410500	Crack Screen						1	
4410500	Flash error						2	
4410500	No Fault Found				3			
4410500	On/off button fault		1		1	1		
4410500	Repaired by Bluepoint		3			1		
4410520	Battery fault			2		2		
4410520	ChipOx reseated							2
4410520	CO2 probe not detected					1		
4410520	Crack Screen					1		
4410520	Display Fault						5	
4410520	Does not power on						1	
4410520	Faulty ISA Module						6	2
4410520	Faulty Pump				1	2	1	
4410520	Flash error				1	5	2	2
4410520	No Fault Found		3			2	2	1
4410520	No Fault Return to Stock							
4410520	On/off button fault		1			1	1	
4410520	Pin stuck in power connector							2
4410520	Repaired by Bluepoint		9	2				
4410520	Replaced connector				2		3	
4410520	Sampling system occlusion							2
4410520	SpO2 sensor not detected				1			
4410520	Unchecked - Returned to Stock							
4410520	Unit to be tested by supplier		1	2	1			
4410520	Water damage							1
4410530	Chemical Damage					1		
4410530	Display Fault						1	
4410530	Does not power on						2	1
4410530	Flash error					5	1	1
4410530	IRMA CO2 calibration						1	
4410530	No Fault Found					1	2	
4410530	No Fault Return to Stock							
4410530	Pin stuck in power connector						1	1
4410530	SpO2 sensor not detected				1		1	
4410540	Battery fault						1	
4410540	Chemical Damage					1		
4410540	Display Fault						1	
4410540	Faulty ISA Module						13	1
4410540	Flash error					1		
4410540	No Fault Return to Stock							
4410540	On/off button fault							1

Stock Reference	Fault	2009	2010	2011	2012	2013	2014	2015
4410540	On/off fault							2
4410540	Replaced connector					1		1
4410540	SpO2 sensor not detected					1		
4410560	CO2 probe not detected					1		
4410560	Flash error					2	1	
4410560	No Fault Found						1	2
4410560	Pin stuck in power connector						1	
4420505	Adapter Error					2	2	
4420505	Failed calibration						1	
4420505	No Fault Found					1	2	
4420505	Physically broken						1	
4420505	Unable to repair				3	3		
4420506	Adapter Error						1	1
4420506	No Fault Found							1
4420511	Unchecked - Returned to Stock							
4420521	Unchecked - Returned to Stock							
4420531	No Fault Return to Stock							
4420590	No Fault Found				1			
4420590	Physically broken				1			
4420590	Unable to repair					1		
4420595	No Fault Found				1			
4420595	No output			1				
4420595	Unable to repair				1			

Comments on Returns:

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

n/a

Comments on Risks with Design Changes:

n/a

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
14945	Capnograph VM-2500 Technical Support Manual	21/04/15
14787	VM2500 4410500 User Maunal English	19/02/15
14786	VM2500 Quick Start Guide V1.0 Booklet	19/02/15
14785	VM-2500 Quick Start Guide V1 0 - Swedish	19/02/15
14783	VM-2500MG Quick Start Guide	19/02/15
13094	Capnograph MG Instructions for Use User Manual	16/10/13
7065	VM2500 4410500 User Maunal Netherlands	29/04/10
7064	VM2500 4410500 User Maunal Italian	29/04/10
7063	VM2500 4410500 User Maunal French	29/04/10
7062	VM2500 4410500 User Maunal Spanish	29/04/10
7061	VM2500 4410500 User Maunal German	29/04/10
6745	4410500 VM2500 Quick Start Guide	08/02/10

Comments on User Instructions:

Adde quick start guides

Comments on Risks User Instructions:

no risks identified with quick start guides

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
14919	Capnograph Labels Sidestream Back of Unit label	13/04/15
14043	Capnograph Labels Mixed File NOMO pe and nasal sampling lines a...	09/06/14
14040	Capnograph Labels 4420571 pouch	09/06/14
14039	Capnograph Labels 4420571 box	09/06/14
14038	Capnograph Labels 4420570 pouch	09/06/14
14037	Capnograph Labels 4420570 box	09/06/14
14036	Capnograph Labels 4420573 pouch	09/06/14
14035	Capnograph Labels 4420573 box	09/06/14
14034	Capnograph Labels 4420572 pouch	09/06/14
14033	Capnograph Labels 4420572 box	09/06/14
14032	Capnograph Labels 4420575 pouch	09/06/14
14031	Capnograph Labels 4420575 box	09/06/14
14030	Capnograph Labels 4420574 pouch	09/06/14
14029	Capnograph Labels 4420574 box	09/06/14
14028	Capnograph Labels 4420576 pouch	09/06/14
14027	Capnograph Labels 4420576 box	09/06/14
14026	Capnograph Labels 4420578 pouch	09/06/14
14025	Capnograph Labels 4420578 box	09/06/14
14024	Capnograph Labels 4420577 pouch	09/06/14
14023	Capnograph Labels 4420577 box	09/06/14
14022	Capnograph Labels 4420579 pouch	09/06/14
14021	Capnograph Labels 4420579 box	09/06/14
14020	Capnograph Labels 4420580 box	09/06/14
14019	Capnograph Labels 4420580 pouch	09/06/14
7081	Capnograph Labels Mainstream Back of Unit label	18/05/10
6775	Capnograph Labels VM 2500S Sample Labels packaging	11/02/10
6774	Capnograph Labels VM 2500 Sample Labels packaging	11/02/10
6773	Capnograph Labels VM 2500 Sample Labels battery	11/02/10
6772	Capnograph Labels VM 2500 Sample Labels serial number	11/02/10

Comments on Labels:

Labels have been updated - new Blue read instructions symbol added

Comments on Risks Labels:

no risks with new labels identified

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
14945	Capnograph VM-2500 Technical Support Manual	21/04/15
14919	Capnograph Labels Sidestream Back of Unit label	13/04/15
14918	Capnograph OES (OEM) Lables for OBLs Overview_labeling_CapnoTrue	13/04/15
14886	Capnograph Expected Life of Products Various Products Blue poin...	27/03/15
14854	Capnograph Data Sheets Carry Case Open House	12/03/15
14787	VM2500 4410500 User Maunal English	19/02/15
14786	VM2500 Quick Start Guide V1.0 Booklet	19/02/15
14785	VM-2500 Quick Start Guide V1 0 - Swedish	19/02/15
14783	VM-2500MG Quick Start Guide	19/02/15
14776	Saudi Arabia Certificate of Registration	19/02/15
14773	Saudia Arabia Registration Certificate for the VM-2500-S & VM-25...	18/02/15
14644	Capnograph Bio-compatibility Sampling lines	31/12/14
14603	BPM DIN EN ISO Deutch BPM Bluepoint Medical ISO 13485	10/12/14
14602	BPM Annex II BPM Notified body certification Blue Point EC Certi...	10/12/14
14594	BPM Declaration of Conformity - Nasal Canulae, CO2 O2 Capnograph...	01/12/14
14585	Capnograph Test Reports Capnotrue ASP	27/11/14
14584	Capnograph External Test Results and Certificates Capnograph Tes...	27/11/14
14561	Capnograph Parts List OEM Price Guide 2	19/11/14
14560	Capnograph Design Input OEM Files VM-2500S-exploded	19/11/14
14559	Capnograph Design Input OEM Files VM-2500M-exploded	19/11/14
14558	Capnograph Design Input OEM Files BluePoint CapnoTrueAMP Explod...	19/11/14
14557	Capnograph Parts List OEM Price Guide	19/11/14
14556	Capnograph Drawings BluePoint CapnoTrueASP Exploded Parts Diagr...	19/11/14
14486	Capnograph External Test Results and Certificates CapnoTrue MG	30/10/14
14459	Capnograph Drawings VM-2500 Hardware Block Diagram	09/10/14
14428	Capnograph Promotional Leaflets Capnograph with Multigas Vet	03/10/14
14427	Capnograph Promotional Leaflets Capnograph Vet	03/10/14
14426	Capnograph Promotional Leaflets Capnograph Accessories - Veteri...	03/10/14
14425	Capnograph Promotional Leaflets Carrying Case for VM-2500	03/10/14
14424	Capnograph Promotional Leaflets Capnograph Multigas Medical	03/10/14
14423	Capnograph Promotional Leaflets Capnograph Medical	03/10/14
14422	Capnograph Promotional Leaflets Capnograph Accessories	03/10/14
14170	Capnograph Software Firmware v8.8 mainstream Medical	18/08/14
14169	Capnograph Software Firmware v8.8 Sidestream Medical	18/08/14
14166	VM2500 Version Log VM2500 Firmware v8.6 - v8.8	18/08/14
14056	Capnograph Test Reports NOMO 3rd Part Test - RedActed	12/06/14
14055	Capnograph Test Reports NOMO 3rd Part Test	12/06/14
14043	Capnograph Labels Mixed File NOMO pe and nasal sampling lines a...	09/06/14
14040	Capnograph Labels 4420571 pouch	09/06/14
14039	Capnograph Labels 4420571 box	09/06/14
14038	Capnograph Labels 4420570 pouch	09/06/14
14037	Capnograph Labels 4420570 box	09/06/14

Document ID	Description	Date Added/Updated
14036	Capnograph Labels 4420573 pouch	09/06/14
14035	Capnograph Labels 4420573 box	09/06/14
14034	Capnograph Labels 4420572 pouch	09/06/14
14033	Capnograph Labels 4420572 box	09/06/14
14032	Capnograph Labels 4420575 pouch	09/06/14
14031	Capnograph Labels 4420575 box	09/06/14
14030	Capnograph Labels 4420574 pouch	09/06/14
14029	Capnograph Labels 4420574 box	09/06/14
14028	Capnograph Labels 4420576 pouch	09/06/14
14027	Capnograph Labels 4420576 box	09/06/14
14026	Capnograph Labels 4420578 pouch	09/06/14
14025	Capnograph Labels 4420578 box	09/06/14
14024	Capnograph Labels 4420577 pouch	09/06/14
14023	Capnograph Labels 4420577 box	09/06/14
14022	Capnograph Labels 4420579 pouch	09/06/14
14021	Capnograph Labels 4420579 box	09/06/14
14020	Capnograph Labels 4420580 box	09/06/14
14019	Capnograph Labels 4420580 pouch	09/06/14
14003	OES OEM EC Declaration of Conformance Accessories for Sidestream...	03/06/14
14000	EC Declaration of Conformance VBM Medizintechnik	03/06/14
13655	Capnograph Post Market Surveillance	22/04/14

Comments on Document Changes:

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 96

Issue ID	Subject
57570	4420550, 4220551 material
55168	4420552 Disposable Airway Adapters
55108	4420552 for stock
54305	A positive mention
58168	Backorder 00000071 4420525 ORD73651
58321	Backorder 00000550 4420525 ORD73737
56468	Backorder 00001810 4420595 ORD72524
56469	Backorder 00001850 4420595 ORD72525
56878	Backorder 00003310 4420620 ORD72806
51970	Backorder 00003490 4420528 ORD69717
54890	Backorder 00003490 4420528 ORD71624
53220	Backorder 00003490 4420595 ORD70422
55059	Backorder 00003490 4420718 ORD71727
52509	Backorder 00006036 4420674 ORD70276
55740	Backorder 00006052 4420613 ORD72098
54044	Backorder 00006052 4420614 ORD70976
58850	Backorder 00006089 4410530 ORD74077
53901	Backorder 00006211 4410520 ORD70397
56184	Backorder 00006673 4420525 ORD72424
51048	Backorder 00007497 4420615 ORD69256
50043	Backorder 00007592 4420595 ORD67997
55055	Backorder 00008012 4420525 ORD71709
51914	Backorder 00011982 4410530 ORD69740
52893	Backorder 00011982 4410530 ORD70367
52892	Backorder 00011982 4410530 ORD70381
58625	Backorder 00011982 4410530 ORD73918
52407	Backorder 00011982 4410540 ORD70039
58485	Backorder 00011982 4420590 ORD73872
53503	Backorder 00011982 4420595 ORD70721
53628	Backorder 00011982 4440000 ORD70721
51911	Backorder 00012456 4410520 ORD69617
56492	Backorder 00012576 4420525 ORD72515
55116	Backorder 00012796 4420552 ORD71651
57451	Box label not working
58262	Call Log 126
52043	Can we discuss 4410520 stock levels please?
50966	Capnographs for demo / training
58660	Chemical Requirements Declaration of Compliance - Masimo
53510	Declaration of Conformity - 4410500, 4410501, 44100530
53511	Declaration of Conformity - 4410520, 4410521, 4410540
50480	Declaration of Conformity - Nasal Canulae
50476	Declaration of Conformity - VBM Medizintechnik

Issue ID	Subject
50095	Demo Stock Required Before end of Day 02/05/14
53327	Demo Stock required for today
55953	Demo VM-2500-S
31108	Disposable sensors price lists
54896	DOC required
53305	Evaluation Items required for Tender in Norway - SOR
58930	Exhibition National Neonatal Simulation Conference Stock Order for Stock to be sent to show
51560	Existing and growing markets for mainstream capnography
57769	Expected service Life: 0012101, 4410500, 4410520, 0012160, 4000 series Reuseable SPO2 sensors
52287	Faults/Technical advice per device faq
51000	Masimo/Phase-In Certificates
50495	Packaging labels & instructions - Nasal Canulae
55874	Pallet - Weight and Dimensions... JSC order
45229	PETO/GHX Export - Requires sending
50971	Please update customer re SRS64392
37635	Predicted sale - VM-2500-S
57852	Request Scanning Item to Sale or return
57851	Request Scanning Item to Sale or return
56915	Request Scanning Item to Sale or return
55997	Request Scanning Item to Sale or return
53411	Request Scanning Item to Sale or return - URGENT
58501	Returned Items SOR457
49514	Returned Items SOR570
51371	Returned Items SOR599
50768	Returned Items SOR603
52086	Returned Items SOR610
55167	Returned Items SOR626
57766	Returned Items SOR631
58075	Returned Items SOR632
57267	Returned Items SOR637
57262	RMA fault page update
54195	Royal Belfast Childrens Hospital
56633	Royal Free
51031	Selection Hygiene
50784	SOR610 - SHA
50783	SOR610 - SHA
57300	Viamed Advert in Ambulance Today
57299	Viamed Advert in Ambulance Today
57298	Viamed Advert in Ambulance Today
57297	Viamed Advert in Ambulance Today
57296	Viamed Advert in Ambulance Today
57295	Viamed Advert in Ambulance Today
57294	Viamed Advert in Ambulance Today
57293	Viamed Advert in Ambulance Today
57292	Viamed Advert in Ambulance Today

Issue ID	Subject
57291	Viamed Advert in Ambulance Today
57290	Viamed Advert in Ambulance Today
57289	Viamed Advert in Ambulance Today
53421	VM2500S for trial
53420	VM2500S for trial
56482	VM2500S for trial - Royal Free
52070	Web Site Question ID 286
58567	Web Site Question ID 474
54251	WMAS capnography tender debrief

Comments on Issues:

mainly SOR or sales issues

Comments on Risks with Issues:

no risks identified within 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 :

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