



VIA MED

## Capnograph

Hand held capnograph and pulse oximeter for continuous and spot-check monitoring of end-tidal CO<sub>2</sub> concentration (EtCO<sub>2</sub>), inspired CO<sub>2</sub> concentration (FiCO<sub>2</sub>), functional arterial oxygen saturation (SpO<sub>2</sub>) respiration rate and pulse rate.

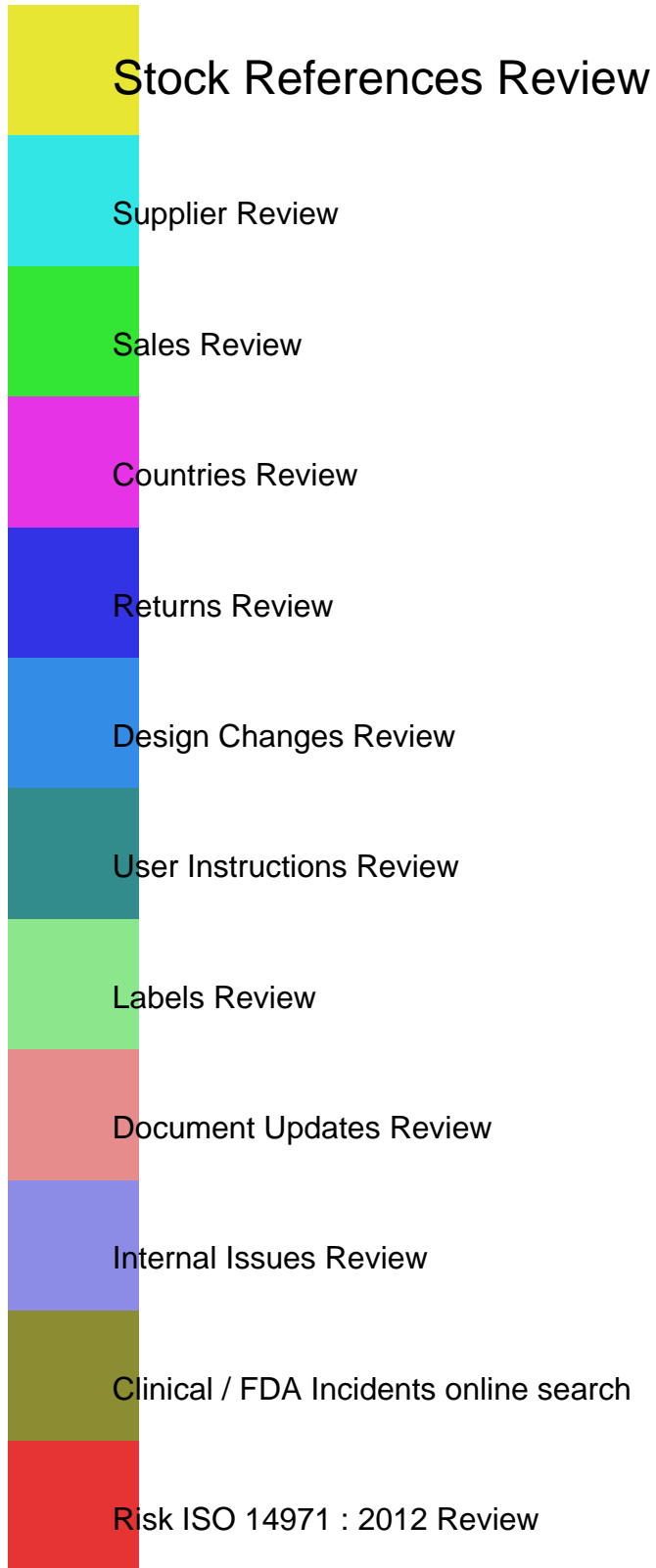
Class IIb

NBOG MD 1302

Carried out by Derek Lamb  
22 / 04 / 14



# VIA MED



# 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
4420525	Nomo adapter for use with VM-2500-S
4420550	Disposable sampling line. Box of 25.
4420730	CO2 Nasal/Oral Sampling Cannula

Comments on Stock references review:

Still the same numbers no new items added,

# Supplier Review

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
4410500	Capnograph VM-2500-M	00009300	Bluepoint Medical	A
4410501	Capnograph VM-2500-M	00009300	Bluepoint Medical	A
4410520	Capnograph VM-2500-S	00009300	Bluepoint Medical	A
4410530	Capnograph VM-2500-M Veterinary version	00009300	Bluepoint Medical	A
4410540	Capnograph VM-2500-S Veterinary version	00009300	Bluepoint Medical	A
4410550	Multigas VM-2500-MG	00009300	Bluepoint Medical	A
4410560	Multigas VM-2500-MG Veterinary version	00009300	Bluepoint Medical	A
4420525	Nomo adapter for use with VM-2500-S	00009300	Bluepoint Medical	A
4420550	Disposable sampling line. Box of 25.	00009300	Bluepoint Medical	A
4420730	CO2 Nasal/Oral Sampling Cannula	00009300	Bluepoint Medical	A

Comments on Suppliers:

Supplier review upto date

# Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
4410500	Capnograph VM-2500-M			16	12	38	49	7
4410501	Capnograph VM-2500-M					2		
4410520	Capnograph VM-2500-S			54	49	54	72	35
4410521	Capnograph VM-2500-S							
4410530	Capnograph VM-2500-M Veterinary version				6	11	4	4
4410540	Capnograph VM-2500-S Veterinary version				1	3	22	4
4410550	Multigas VM-2500-MG					3	7	
4410560	Multigas VM-2500-MG Veterinary version						2	
4420525	Nomo adapter for use with VM-2500-S			66	26	111	254	104
4420550	Disposable sampling line. Box of 25.			16	19	35	33	49
4420730	CO2 Nasal/Oral Sampling Cannula				2	11	11	7

Comments on Sales Information:

Units increasing in sales

# Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
			[X]	[X]	[X]	[X]	
B Belgium			[X]	[X]		[X]	[X]
BA State of Bahrain						[X]	
C China						[X]	[X]
CAN Canada						[X]	[X]
CRO Croatia				[X]			
CZ Czech Republic			[X]				
DE Denmark			[X]				
ES Estonia						[X]	[X]
F France						[X]	[X]
FI Finland			[X]	[X]	[X]	[X]	[X]
G Germany			[X]		[X]	[X]	[X]
GR Greece			[X]				
HK Hong Kong					[X]		
I Iran			[X]				
IN India				[X]			
IND Indonesia						[X]	
IQ IRAQ						[X]	[X]
IRE Ireland				[X]	[X]	[X]	[X]
IS Israel			[X]				
KU Kuwait				[X]			
LEB Lebanon			[X]		[X]		
MA Malaysia			[X]	[X]	[X]		
MAU Mauritius						[X]	
NE Netherlands			[X]		[X]		[X]
NO Norway			[X]	[X]	[X]	[X]	[X]
NZ New Zealand						[X]	
OM Oman			[X]			[X]	
RO Romania						[X]	
RU Russia						[X]	
SA South Africa				[X]	[X]		
SAU Saudi Arabia			[X]	[X]	[X]	[X]	[X]
SP Spain			[X]			[X]	
SRI Sri Lanka					[X]		
SW Sweden			[X]	[X]	[X]	[X]	
SWI Switzerland							[X]
SY Syria			[X]	[X]			
T Turkey			[X]	[X]	[X]	[X]	
TH Thailand				[X]	[X]	[X]	
UAE U A E					[X]	[X]	[X]
UK United Kingdom			[X]	[X]	[X]	[X]	[X]
VI Vietnam					[X]	[X]	

Comments on Sales to Countries:

New countries still coming on board,

Comments on Risks with Sales to Countries:

No risks identified with teh various new couhntries

# Returns Review

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
4410500	CO2 probe not detected			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	CO2 probe not detected						1	
4410520	Crack Screen						1	
4410520	Display Fault							2
4410520	Faulty Pump					1	2	
4410520	Flash error					1	5	
4410520	No Fault Found			3			2	1
4410520	No Fault Return to Stock							
4410520	On/off button fault			1			1	
4410520	Repaired by Bluepoint			9	2			
4410520	Replaced connector					2		1
4410520	SpO2 sensor not detected					1		
4410520	Unchecked - Returned to Stock							
4410520	Unit to be tested by supplier			1	2	1		
4410530	Chemical Damage						1	
4410530	Flash error						5	
4410530	No Fault Found						1	1
4410530	SpO2 sensor not detected					1		
4410540	Chemical Damage						1	
4410540	Faulty ISA Module							2
4410540	Flash error						1	
4410540	Replaced connector						1	
4410540	SpO2 sensor not detected						1	
4410560	CO2 probe not detected						1	
4410560	Flash error						2	1

Comments on Returns:

Returns are very Low,

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

# User Instructions Review

## Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
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
7060	VM2500 4410500 User Maunal English	29/04/10
6745	4410500 VM2500 Quick Start Guide	08/02/10

Comments on User Instructions:

Multi Gas Instrutions Added,  
User Manuals are still fit for purpose

Comments on Risks User Instructions:

n/a

# Labels Review

## Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
7082	Capnograph Labels Sidestream Back of Unit label	18/05/10
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:

No label Changes

Comments on Risks Labels:

n/a

# Documentation Updates / Changes

Comments on Document Changes:

Very few changes in the documentation

Comments on Risks with Document Changes:

n/a

# Internal Issues Review

Number of Issues reviewed: 25

Issue ID	Subject
49514	Returned Items SOR570
47383	Returned Items SOR579
46983	Returned Items SOR588
46955	Returned Items SOR589
46852	Returned Items SOR563
46677	Returned Items SOR581
46550	Returned Items SOR572
46419	Request Scanning Item to Sale or return
46097	Returned Items SOR558
45485	Returned Items SOR573
45152	Returned Items SOR567
44513	Theramed - SOR581
42989	Request Scanning Item to Sale or return
42761	Returned Items SOR548
42669	Returned Items SOR544
42631	Returned Items SOR562
42579	Request Scanning Item to Sale or return
42415	Returned Items SOR559
43425	Capnograph Section
43009	Split pack into singles
42381	Declarations of Conformity required
42380	Declarations of Conformity required
42354	PMS Viamed OBL product Capnograph Sales Information
47640	Wrong quantity in packs
32904	Capnograph Mainstream - web site additions & images

Comments on Issues:

sale or returns issues mainly, a few stock movement 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 :

## 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