



# VIA MED

## FlowSensors

Flowsensor A, hot-wire flowsensor to measure gas flow in breathing systems.

Class IIa

NBOG MD 0101

Carried out by Derek Lamb  
16 / 09 / 14



# VIA MED

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# Stock References Review

Stock Reference	Description
4310001	Flowsensor SpiroTrue A. Pack of 5.
4310002	Flowsensor SpiroTrue A (PC). Pack of 5.
4310003	Flowsensor SpiroTrue H. Pack of 6.
4330001	Flowsensor SpiroTrue A.
4330002	Flowsensor SpiroTrue A (PC).
4330003	Flowsensor SpiroTrue H.

Comments on Stock references review:

Stock items are correct for review

# Supplier Review

Stock Reference	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
4310001	Flowsensor SpiroTrue A. Pack of 5.	00009300	1030132006	Bluepoint Medical	A
4310002	Flowsensor SpiroTrue A (PC). Pack of 5.	00009300		Bluepoint Medical	A
4310003	Flowsensor SpiroTrue H. Pack of 6.	00009300	1030132000	Bluepoint Medical	A

Comments on Suppliers:

Supplier review is upto date

# Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
4310001	Flowsensor SpiroTrue A. Pack of 5.		212	684	1178	1183	914	30
4310002	Flowsensor SpiroTrue A (PC). Pack of 5.						67	583
4310003	Flowsensor SpiroTrue H. Pack of 6.		4		259	276	301	247
4330001	Flowsensor SpiroTrue A.		6	8	3	6	2	
4330002	Flowsensor SpiroTrue A (PC).							4
4330003	Flowsensor SpiroTrue H.		1	1	6	1		7

## Comments on Sales Information:

Due to single use issues, and complying with the CE we decided to drop the SpiroTrue A, and only sell the slightly more expensive version which is autoclavable.

There was no risk in using the A however there was a question of re-use.

Depending on the device the Flowsensor is used on dictates if the flowsensor can be re-used. MHRA not happy with the instructions referring to the original machines instructions on cleaning / re-use.

so the product has been effectively dropped for the UK market.

# Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
AL Algeria				[X]			
AU Austria		[X]					
B Belgium				[X]			
EG Egypt				[X]	[X]		
ES Estonia				[X]			
F France							[X]
G Germany		[X]				[X]	
GEO Georgia				[X]			
GR Greece			[X]	[X]	[X]	[X]	[X]
IN India		[X]	[X]				
IND Indonesia							[X]
IT Italy							[X]
JO Jordan				[X]	[X]		
KE Kenya							[X]
LIB Libya							[X]
MA Malaysia		[X]					
MO Morocco				[X]	[X]	[X]	[X]
NO Norway			[X]				
P Poland					[X]		[X]
PA Pakistan				[X]			
PH Philippines						[X]	
PO Portugal							[X]
RO Romania					[X]	[X]	[X]
SAU Saudi Arabia			[X]	[X]			[X]
SER Serbia				[X]		[X]	[X]
SP Spain				[X]	[X]	[X]	[X]
SRI Sri Lanka						[X]	[X]
T Turkey		[X]	[X]	[X]	[X]	[X]	[X]
UAE U A E							[X]
UK United Kingdom		[X]	[X]	[X]	[X]	[X]	[X]
VI Vietnam					[X]		

Comments on Sales to Countries:

Picked up new countries France Indonesia Italy Kenya Libya Philippines Portugal and the U A E

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
4310001	No Fault Return to Stock							
4310001	Unchecked - Returned to Stock							
4330001	Failed calibration		1					
4330001	Investigated					1		
4330001	No Fault Found					2		

## Comments on Returns:

Plastic T piece with active flow sensor, does not warrant being returned when used. so returns figures do not reflect the reality of failures.

We did have a issue with the Flowsensor A braking. See Issue 43051

## Comments on Risks with Returns and Potential Re-work:

No risks identified with the failures.

# Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No documented 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
13198	SpiroTrue / Flowsensor A Flowsensor User Instruction	03/12/13
13196	FlowSensors Instructions for Use User Manual APC	03/12/13
7696	SpiroTrue / Flowsensor H Flowsensor user instructions	17/02/11

Comments on User Instructions:

User manuals have been updated after discussions with the MHRA - regarding the single-use / re-use scenarios

Comments on Risks User Instructions:

no risks identified

# Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
7084	FlowSensors Labels flowsensorH	18/05/10
6586	FlowSensors Labels IMAG0103 Packet label	08/10/09
6585	FlowSensors Labels IMAG0102 Box label	08/10/09

Comments on Labels:

No label changes

Comments on Risks Labels:

N/a

# Documentation Updates / Changes

Document ID	Description	Date Added/Updated
13373	FlowSensors Competitor Instructions for use for similar products...	27/03/14
13371	FlowSensors Competitor Instructions for use for similar products...	27/03/14
13370	FlowSensors Competitor Instructions for use for similar products...	27/03/14
13369	FlowSensors Competitor Instructions for use for similar products...	27/03/14
13198	SpiroTrue / Flowsensor A Flowsensor User Instruction	03/12/13
13196	FlowSensors Instructions for Use User Manual APC	03/12/13
13194	FlowSensors OES (OEM) Instructions for Use SpiroTrueAPC	03/12/13
13192	FlowSensors A OES (OEM) Instructions for Use / User Manual	03/12/13
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
12384	FlowSensors Clinical Trials Reports Reviews and Post Market Surv...	23/05/13

Comments on Document Changes:

Competitor instructions have been uploaded into the file for comparison - due to the MHRA queries.

Comments on Risks with Document Changes:

No risks identified in the documentation

# Internal Issues Review

Number of Issues reviewed: 38

Issue ID	Subject
48001	Request Scanning Item to Sale or return
47670	Request Scanning Item to Sale or return
47357	Request Scanning Item to Sale or return
48470	Flowsensors - instructions for single qty samples
44281	Reserve - Flowssensor A PRO02384
43102	Flowsensor A
43101	Flowsensor A
45021	Peto Export Items require attention
44868	Sales tagged to Vandagraph instead of Viamed
44817	Group Peto Group - Export
44487	Stock File - Descriptions
44486	e-class code - 2 parts
50049	Flowsensor A(PC) accuracy problems
45184	Worcestershire Royal Hospital
43051	4310001 MHRA Ref 2013/005/020/401/001 Flowsensor Failure
47894	Flow sensor issue closing letter
38431	Flowsensor A Sales
45185	Stock barcodes to delete
44838	QA Stock locations
50893	Flowsensor A(PC) batch information
50892	Flowsensor A(PC) batch information
50891	Flowsensor A(PC) batch information
50890	Flowsensor A(PC) batch information
47950	Flowsensor cleaning
47143	Flowsensor disinfection procedure
43851	Flowsensor Meetings - Naming of Flowsensors
43587	Flowsensor Meetings
48168	Flowsensor Distributor Price Lists - Amendment Needed
47517	4310002 replacing 4310001
47627	4310002 draft letter ref. superseding 4310001
50807	4310002 - Draeger Flow Sensor - Declaration of Compatibility
50806	4310002 - Draeger Flow Sensor - Declaration of Compatibility
49118	Flow Sensor - 4310002 - Draeger Compatible Autoclavable
48663	Flowsensor A, APC - sales lead India
48469	Greece - Temperature probes
48466	Greece - temperature probes
43569	4310002 Autoclavable Flow Sensors for Draeger
51007	Spirotrue Flow Sensors

Comments on Issues:

Mainly stock movement / marketing Issues.  
and the expected cleaning / instructions issues

Comments on Risks with Issues:

no risks Identified

# 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 :

Component of existing equipment, will not go out of date until the original units are removed from service

Known risk of being flammable: <http://www.ncbi.nlm.nih.gov/pubmed/20853769>

Health Devices. 2009 Oct;38(10):339-40.

Hazard report. Flammable material introduced into draeger ventilator and anesthesia unit flow sensors could ignite, posing risks to patients.

ECRI Institute.

### Abstract

In rare cases, when flammable material is introduced into the Spirolog or SpiroLife flow sensor used with Draeger Medical ventilators and anesthesia units, the material could ignite, posing the risk of patient injury or device damage. Users can reduce this risk by carefully inspecting circuit components before use, by not introducing flammable products into the circuit during use, and by strictly complying with the company's instructions to allow the sensors to dry completely following alcohol disinfection.

This is a known risk and on all labelling and instructions of both our compatibles and the original Drager devices.

## Review of online FDA Incident reports

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

52430

Risk Search Yes

Out of Date Search No

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_\\_id=2747985](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2747985)

Report refers to Drager ISO 15 Flowsensor. We do not do an equivalent device to this sensor so the report does not apply to our products.

# Risk ISO 14971 : 2012 Review

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