

Post Market Surveillance Review

4310001 Flowsensor SpiroTrue A. Box of 5

First sold: **12th January 2009**

General sales suspended 18th December 2013 due to MHRA stance on single use designation.

Total sales to date: **5,906 boxes, across 34 countries**

Total failures: **6 boxes**

Total returns: **6 boxes**

Total customer failures: **0.102%**

Liverpool Heart & Chest Hospital SRS63066, received 1 box 10th October 2011

Failed calibration. Also reported sensors generally have shorter life than Draeger OEM sensors.

Result: Customer lost, approximately 100 boxes per year. Resumed using Draeger OEM sensors, will try and regain the sales with Flowsensor SpiroTrue A.

Dorset County Hospital SRS63869, received 1 box 3rd June 2013

Failed calibration.

Result: Customer lost, approximately 12 boxes per year. Will try and regain the sales with Flowsensor SpiroTrue A.

Papworth Hospital SRS64002, received 4 boxes 11th September 2013

Failed calibration when used on Evita 4s.

Result: Customer lost, approximately 120 boxes per year. They have tried both SpiroTrue A and SpiroTrue A (PC). Will try and regain the sales with Flowsensor SpiroTrue A.

Applications:

Manufacturer	Description	
Acutronic	1601+	Flow Sensor
Acutronic	SpiroQuant A	Flow Sensor
Asmuth GmbH Medinzintechnik	AS432+	Flow Sensor
Asmuth GmbH Medinzintechnik	AS8403735	Flow Sensor
Asmuth GmbH Medinzintechnik	SpiroTrue A	Flow Sensor
Draeger	Spirolog 84 03 735	Flow Sensor
Draeger	8403735	Flow Sensor
Draeger	Anemone	Monitor
Draeger	Apollo	Anaesthesia System
Draeger	AV1	Anaesthesia System
Draeger	Cato	Anaesthesia System
Draeger	Cicero	Anaesthesia System
Draeger	D-9118-2009	Flow Sensor
Draeger	Dura	Ventilator
Draeger	Eva	Ventilator
Draeger	Evita	Ventilator

Draeger	Evita 4	Ventilator
Draeger	Evita XL	Ventilator
Draeger	Fabius GS	Anaesthesia System
Draeger	Infinity ID (NOTE Viamed does not have RFID)	Flow Sensor
Draeger	Infinity V500 (NOTE Viamed does not have RFID)	Anaesthesia System
Draeger	Julian	Anaesthesia System
Draeger	MT-2086-2007 (NOTE Viamed does not have RFID)	Flow Sensor
Draeger	PM 8030	Monitor
Draeger	PM 8035	Monitor
Draeger	PM 8050	Monitor
Draeger	PM 8060	Monitor
Draeger	Primus	Anaesthesia System
Draeger	Savina	Ventilator
Draeger	Spirolog	Flow Sensor
Draeger	Spirolog 8403735	Flow Sensor
Draeger	Sulla	Anaesthesia System
Envitec	1000470	Flow Sensor
Envitec	SpiroQuant A+	Flow Sensor
Integral Process	0032 00 02	Flow Sensor
Integral Process	65025	Flow Sensor
Integral Process	8403735	Flow Sensor
Intersurgical	2777000	Flow Sensor
Intersurgical	e-FlowSensor	Flow Sensor
Medacx	M-45-00-0005	Flow Sensor
Medacx	SpiroQuant A	Flow Sensor
Proact Medical	1000470	Flow Sensor
Proact Medical	SpiroQuant A+	Flow Sensor

Reviewed by: Steve Nixon
Director – Viamed Ltd.

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