

Post Market Surveillance Review to 31st December 2020

4310001 Flowsensor SpiroTrue A. Box of 5

Bluepoint Medical ref.: 1030132006

First sold: 12th January 2009

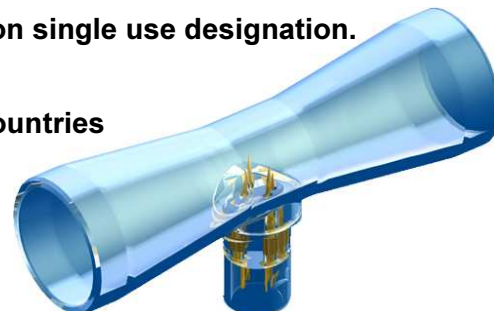
General sales suspended 18th December 2013 due to MHRA stance on single use designation. Reinstated when covered by Bluepoint Medical CE certification.

Total sales to date: **4,686 boxes, 111 different customers across 34 countries**

Total failures: **6 boxes**

Total returns: **6 boxes**

Total customer failures: **0.128%**



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.

For the period from 12th September 2013 to 31st December 2020, there has not been any new reported failures or failures that refer to the claims listed above.

The design, functionality and reliability of the sensor is very good. We do include feedback forms within each box of sensors for end users to be able to easily report possible issues and/or for confirming compatibility. Unfortunately, we get very few feedback forms returned as the customers are happy with the sensors and have nothing to report.

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
Biometric Cables	910246001	Flow Sensor
Biometric Cables	FS1	Flow Sensor
Bluepoint Medical	1030132006	Flow Sensor
Bluepoint Medical	6871980 (NOTE Viamed does not have RFID)	Flow Sensor
Bluepoint Medical	PM 8030	Monitor
Bluepoint Medical	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 ver. does not have RFID)	Flow Sensor
Draeger	Infinity V500 (NOTE Viamed ver. does not have RFID)	Anaesthesia System
Draeger	Julian	Anaesthesia System
Draeger	MT-2086-2007 (NOTE Viamed ver. 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
Lub Dub Medical	OX-2529	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
Viamed	1030132006	Flow Sensor
Viamed	Flowsensor A	Flow Sensor
Viamed	SpiroTrue A	Flow Sensor

Reviewed by: Steve Nixon

Director – Viamed Ltd

Date: 5th February 2021

