



# VIAMED



**Post Market Surveillance Review to 21<sup>st</sup> March 2024**

**4310002, 4310009 Flowsensor SpiroTrue A (PC). Box of 5**

Bluepoint Medical references: **7030131001, 3030131003**

First sold: **24<sup>th</sup> May 2013**

Total sales to date: **13,435 boxes,**  
**91 different customers across 30 countries**

Total failures: **10 boxes**

Total returns: **10 boxes**

Total customer failures: **0.074%**

**Royal Brompton Hospital SRS64245, received 1 box 19th March 2014**

Inaccurate tidal volume readings. Sometimes on 500ml inspired volume, the A(PC) will read up to 590ml, other times just a little out, e.g. +10ml. It is not an issue with the ventilators, as the problems do not exist when they revert back to original Draeger flowsensors. Customer originally purchased Flowsensor SpiroTrue A, but switched to SpiroTrue A (PC) due to MHRA stance on single use designation.

**Result:** Customer stopped purchasing, their requirements is about 60 boxes per year. Will try and regain the sales, with either Flowsensor SpiroTrue A or Flowsensor SpiroTrue A (PC).

**James Paget Hospital SRS64307, received 5 boxes 16<sup>th</sup> May 2014**

Calibration issues when used with Evita 4. Customer originally purchase Flowsensor SpiroTrue A, but switched to SpiroTrue A (PC) due to MHRA stance on single use designation.

**Result:** Customer retained.

**Royal Bournemouth SRS64386, received 4 boxes 15<sup>th</sup> July 2014**

Calibration issues on Draeger Evita XL, this happened on six different ventilators. Some failed initial calibration, other failed shortly afterwards. Customer originally purchase Flowsensor SpiroTrue A, but switched to SpiroTrue A (PC) due to MHRA stance on single use designation.

**Result:** Customer stopped purchasing, their requirements is about 15 boxes per year. Will try and regain the sales, with either Flowsensor SpiroTrue A or Flowsensor SpiroTrue A (PC).

**For the period from 16<sup>th</sup> July 2014 to 21<sup>st</sup> March 2024, 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:**

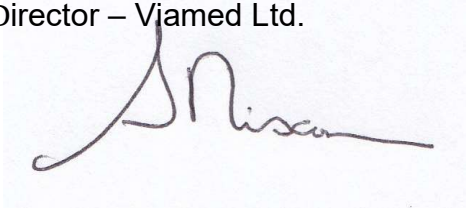
<b>OEM</b>	<b>OEM Part Number</b>	<b>Equipment Type</b>
Acutronic	Evita range	Ventilator
Acutronic	Savina range	Ventilator
Asmuth GmbH Medinzintechnik	2 42516796 0167 2	Flow Sensor
Asmuth GmbH Medinzintechnik	6030131004	Flow Sensor
Asmuth GmbH Medinzintechnik	AS432+-AUTO	Flow Sensor
Asmuth GmbH Medinzintechnik	AS434	Flow Sensor
Asmuth GmbH Medinzintechnik	SpiroTrue APC	Flow Sensor
Bluepoint Medical	2 42516796 0157 7	Flow Sensor
Bluepoint Medical	3030131003	Flow Sensor
	(sold 1 piece per box)	
Bluepoint Medical	SpiroTrue APC	Flow Sensor
Draeger	Apollo	Anaesthesia System
Draeger	AV1	Anaesthesia System
Draeger	Cato	Anaesthesia System
Draeger	Cicero	Anaesthesia System
Draeger	D-9119-2009	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	Fabius range	Anaesthesia System
Draeger	Julian	Anaesthesia System
Draeger	MK01900	Flow Sensor
	(autoclavable version of Spirolog)	
Draeger	Perseus A500	Anaesthesia System
Draeger	PM 8030	Monitor
Draeger	PM 8035	Monitor
Draeger	PM 8050	Monitor
Draeger	PM 8060	Monitor
Draeger	Primus	Anaesthesia System
Draeger	Primus / Apollo	Anaesthesia System
Draeger	Savina	Ventilator
Draeger	SpiroLife	Flow Sensor
	(autoclavable version of Spirolog)	
Draeger	SpiroLife MK 01900	Flow Sensor
Draeger	SpiroLife MK01900	Flow Sensor
Draeger	Sulla	Anaesthesia System
Draeger	Zeus	Anaesthesia System

Viamed  
Viamed  
Viamed  
Viamed

2 42516796 0168 9  
7030131001  
Flowsensor A (PC)  
SpiroTrue A (PC)

Flow Sensor  
Flow Sensor  
Flow Sensor  
Flow Sensor

Reviewed by: Steve Nixon  
Director – Viamed Ltd.

A handwritten signature in dark ink, appearing to read 'S Nixon', is written over a light blue rectangular background.

Date: 21<sup>st</sup> March 2024