



Post Market Surveillance Review to 21st March 2024

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

Bluepoint Medical references: **7030131001, 3030131003**

Autoclavable

First sold: **24th 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 16th 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 15th 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 16th July 2014 to 21st 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.

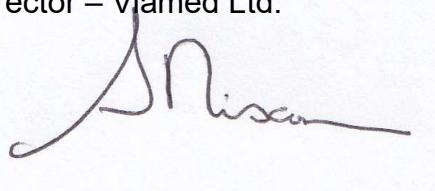
Applications:

| OEM | OEM Part Number | Equipment Type |
|-----------------------------|---|-----------------------|
| 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 (sold 1 piece per box) | Flow Sensor |
| 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 (autoclavable version of Spirolog) | Flow Sensor |
| 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 (autoclavable version of Spirolog) | Flow Sensor |
| Draeger | SpiroLife MK 01900 | Flow Sensor |
| Draeger | SpiroLife MK01900 | Flow Sensor |
| Draeger | Sulla | Anaesthesia System |
| Draeger | Zeus | Anaesthesia System |

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|--------|-------------------|-------------|
| Viamed | 2 42516796 0168 9 | Flow Sensor |
| Viamed | 7030131001 | Flow Sensor |
| Viamed | Flowsensor A (PC) | Flow Sensor |
| Viamed | SpiroTrue A (PC) | Flow Sensor |

Reviewed by: Steve Nixon

Director – Viamed Ltd.

A handwritten signature in black ink, appearing to read "Steve Nixon".

Date: 21st March 2024