Post Market Surveillance Review to **31st December 2020**

4310002 Flowsensor SpiroTrue A (PC). Box of 5

Bluepoint Medical ref.: **7030131001**

First sold: **24th May 2013**

Total sales to date: **10,435 boxes,**

91 different customers across 30 countries

Total failures: **10 boxes**

Total returns: **10 boxes**

Total customer failures: **0.096%**

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).
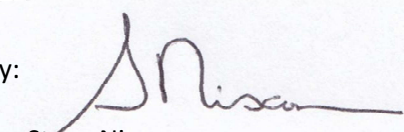
For the period from 16th July 2014 to 31st December 2020, there has not been any new reported failures or failures that refer to the claims listed above.

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	
Asmuth GmbH Medinzintechnik	AS432+-AUTO	Flow Sensor
Asmuth GmbH Medinzintechnik	AS434	Flow Sensor
Asmuth GmbH Medinzintechnik	SpiroTrue APC	Flow Sensor
Draeger	Apollo	Anaesthesia System
Draeger	AV1	Anaesthesia System
Draeger	Cato	Anaesthesia System
Draeger	Cicero	Anaesthesia System
Draeger	Dura	Ventilator
Draeger	Eva	Ventilator
Draeger	Evita	Ventilator
Draeger	Evita 4	Ventilator
Draeger	Evita XL	Ventilator
Draeger	Fabius GS	Anaesthesia System
Draeger	Julian	Anaesthesia System
Draeger	MK01900 (autoclavable version of Spirolog)	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	SpiroLife (autoclavable version of Spirolog)	Flow Sensor
Draeger	SpiroLife MK01900	Flow Sensor
Draeger	Sulla	Anaesthesia System
Viamed	7030131001	Flow Sensor
Viamed	Flowsensor A (PC)	Flow Sensor
Viamed	SpiroTrue A (PC)	Flow Sensor

Reviewed by:

Steve Nixon
Director – Viamed Ltd.

Date: 5th February 2021