

## Post Market Surveillance Review

### 4310002 Flowsensor SpiroTrue A (PC). Box of 5

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

Total sales to date: **3,553 boxes, across 24 countries**

Total failures: **10 boxes**

Total returns: **10 boxes**

Total customer failures: **0.281%**

#### **Royal Brompton Hospital SRS64245, received 1 box 19<sup>th</sup> 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).

#### 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

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Date: 21<sup>st</sup> July 2017