



Post Market Surveillance Review to 21st March 2024

4310003, 4310009 Flowsensor SpiroTrue H. Box of 6

Bluepoint Medical ref.: **1030132000, 3030131005**

First sold: **8th May 2009**

Total sales to date: **9,218 boxes, 53 different customers across 31 countries**

Total failures: **2 boxes**

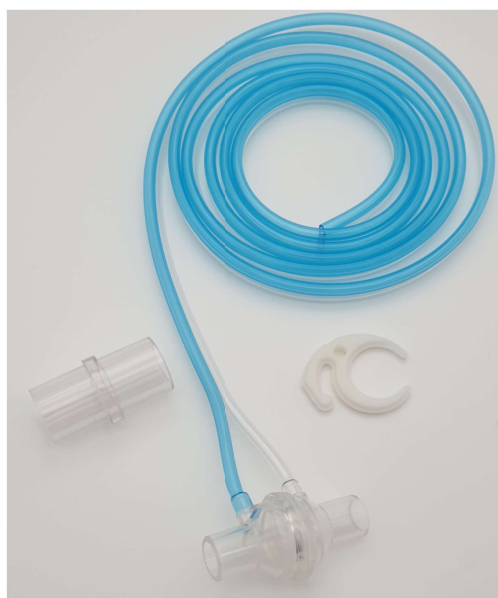
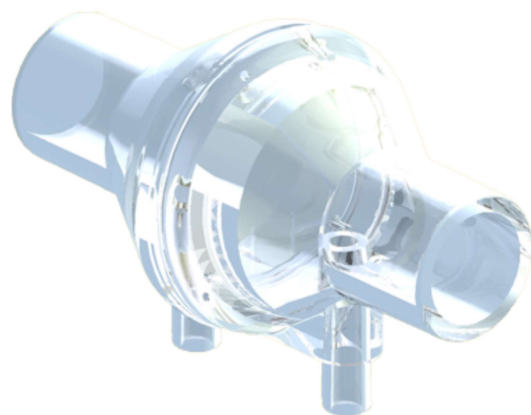
Total returns: **2 boxes**

Total returns: **2 packs – failed calibration on Hamilton G5 ventilator, reported then returned to Viamed for credit 10/12/2009. Sensors supplied to Bluepoint Medical for evaluation 29/12/2009 Customer: Royal Sussex County Hospital SRS61983**

Total customer failures: **0.02%**

For the period from 30th December 2009 to 11st March 2022, there has not been any new reported failures or failures that refer to the claims listed above.

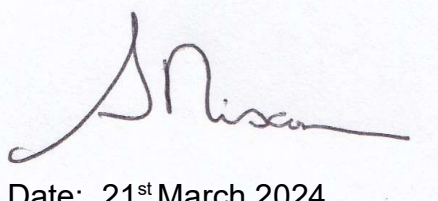
The design, functionality and reliability of the sensor is very good. We do include feedback forms within each box of sensors for end users to be able to easily report possible issues and/or for confirming compatibility. Unfortunately, we get very few feedback forms returned as the customers are happy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



Applications:

OEM	OEM Part Number	Equipment Type
Asmuth GmbH Medinzintechnik	2 42516796 0163 4	Flow Sensor
Asmuth GmbH Medinzintechnik	4030131003	Flow Sensor
Asmuth GmbH Medinzintechnik	SpiroTrue H	Flow Sensor
Biometric Cables	910246002	Flow Sensor
Biometric Cables	FS2	Flow Sensor
Bluepoint Medical	1030132000	Flow Sensor
Bluepoint Medical	2 422516796 0156 6	Flow Sensor
Bluepoint Medical	SpiroTrue H	Flow Sensor
Draeger	Oxylog 2000 Plus (if disposable circuits used)	Ventilator
Draeger	Oxylog 3000 (if disposable circuits used)	Ventilator
Draeger	Oxylog 3000 Plus (if disposable circuits used)	Ventilator
Draeger	VentStar	Ventilator
Hamilton Medical	155362	Flow Sensor
Hamilton Medical	279331	Flow Sensor
Hamilton Medical	53120	Flow Sensor
Hamilton Medical	Amadeus	Ventilator
Hamilton Medical	C1	Ventilator
Hamilton Medical	C2	Ventilator
Hamilton Medical	G5	Ventilator
Hamilton Medical	Galileo	Ventilator
Hamilton Medical	H72	Ventilator
Hamilton Medical	H7200	Ventilator
Hamilton Medical	H7400 AccuTach	Flow Sensor
Hamilton Medical	MR1	Ventilator
Hamilton Medical	Raphael	Ventilator
Hamilton Medical	S1	Ventilator
Hamilton Medical	T1	Ventilator
Hamilton Medical	Veolar	Ventilator
Hamilton Medical	VR-1	Ventilator
Lub Dub Medical	OX-2530	Flow Sensor
Med-Shopping	MAC-VTA-OTH-FSH7200	Flow Sensor
Viamed	1030132000	Flow Sensor
Viamed	2 422516796 0164 0	Flow Sensor
Viamed	3030131005	Flow Sensor
Viamed	Flowsensor H	Flow Sensor
Viamed	SpiroTrue H	Flow Sensor

Reviewed by: Steve Nixon
Director – Viamed Ltd.



Date: 21st March 2024