



Viamed Limited - 15 Station Road - Cross Hills
Keighley - West Yorkshire BD20 7DT - United Kingdom
Tel: 01535 634542 Fax: 01535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

Miss Sandra Draper
Admin Team Leader
MHRA Adverse Incident Centre
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

20th February 2012

MHRA Ref 2012/001/030/031/001 (& 2012/001/018/401/002)

Medical device adverse incident report from Nottingham University Hospitals Trust – City Campus
(their ref: 34655 NUHWEB18288 17/01/2012).

Dear Miss Draper

The following is further to your email dated the 30th January 2012 concerning the above reported adverse incident.

Part 1 Reported Adverse Event

A. Device Details:

Flowsensor A
Part number: 4330001 (pack of 5 sensors)
Bar code I.D. 477634
Lot: 2035530216, Manufacture date: 07-2011
Customer order reference: 200269473
Customer account: 00003910
Invoice: IN117596 dated 16/09/11

Delivery Address:

Nottingham University Hospital
Medical Physics/Clinical Engineering
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

Is the device CE marked under any of the Medical Devices Directives?	YES	Identity of Notified Body CE0086 British Standards Institute	
Date first sold in UK	08/06/09		
No. devices in UK Since first sold	9,440	No. similar incident in UK	NONE
No. devices in EU Since first sold	160	No. similar incidents in EU	NONE
No. devices worldwide Since first sold	1,475	No. similar incidents worldwide	NONE
Date of manufacture	07-2011	Date the problem or adverse incident occurred or was detected	18/01/12 Date reported to Viamed

B. Investigation of the cause of the Incident

The sensor in question was received at Viamed on the 16th February 2012, together with two other sensors from the same box; one sealed in its original packaging and the other which has had its packaging opened. It is assumed the two other sensors from the same box have been used.

The sensors were returned in their original packaging box - which included the instructions for use.

The sensor returned for investigation, was returned in a clear plastic bag and was marked:
NUHWEB 18288

The sensor box was marked: **JOB No. 520224**

The letter received together with the sensors from Mr Adrian Morgan stated:

"Please perform an examination and provide a full written report on any findings. This was due to an untoward incident and there was no patient harm."

Upon goods-in inspection the sensors were ATP swabbed for contaminants, the results were as follows:

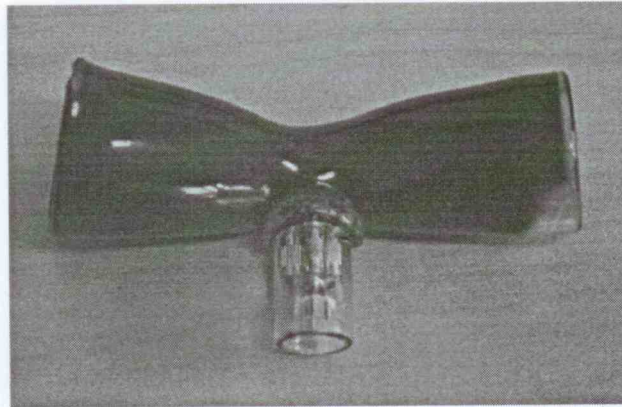
Viamed's tracking references	Sensor Condition	Sensor internal surfaces (RLU)	Sensor external surfaces (RLU)	Test result
SRN20691 Tracking 1	Fire damage - sensor for investigation	3	32	FAIL
SRN20692 Tracking 2	Received opened, believe unused.	8	11	PASS
SRN20693 Tracking 3	Received unopened	6	0	PASS
Goods-in limits 15 – 30 RLU				



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Upon initial inspection the unused sensors do not indicate any abnormalities. The sensor that caught fire and returned for investigation does indeed exhibit fire damage - as can be clearly seen by the pictures below.



We will conduct further tests. However, initial thoughts are that perhaps a contaminate fuel source was inadvertently introduced, say if the sensor was used immediately after being disinfected. It also has to be considered whether the breathing system (patient circuit or ventilator parts) was disinfected immediately prior to use. In the Draeger instructions for use relating to the ventilator, there is a warning about possible fire hazard after flow sensor disinfection... In addition, included in with each box of sensors - the instructions for use clearly states that there is a possible fire risk, if medicaments or other substances based on combustible solvents, such as alcohol are introduced into the patient systems.

As far as we are aware there isn't anything in regard to the sensor manufacturing materials that could cause this incident.

C. Risk Assessment

From the letter received with the returned sensors **"there was no patient harm."**

The outcome is not yet known in regard to the user or others involved in the incident.

To our knowledge, to-date this is an isolated event; we have not heard of a similar event concerning our sensors.

If the sensors are used in line with the instructions for use (copy attached), then there should not be a reoccurrence; whether Viamed sensors are used or whether Draeger sensors are used



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The flow sensor box package labelling is illustrated with the 'consult instructions for use' symbol (as per EN.980:2008)



In the ventilator's instructions for use there are clear warning statements, for example:

WARNING

After disinfecting with highly flammable substances, air the flow sensor for at least 30 minutes or rinse with sterile water. Otherwise, vapors could ignite during calibration. Fire hazard!

WARNING

Never use flammable medications (e.g. on the basis of isopropyl alcohol) or other substances based on flammable solvents in the breathing system. Always provide adequate ventilation when using flammable substances for disinfection. Flammable vapors may otherwise ignite when calibrating the flow sensor and destroy the flow sensor in the process. Fire hazard!

WARNING

Never nebulize flammable medications! Fire hazard from hot wire anemometer in the flow sensor!

WARNING

Contamination may lead to deviations during flow measurement and to destruction of the flow sensor.

Can it be confirmed that the incident happened during conditioning and calibration of a newly installed sensor? The ventilators logbook should be able to verify this - as it records changes, events and alarms and lists them in chronological order with the date and time of occurrence. The last 1000 entries are permanently saved. Preceding entries are automatically deleted. Events include, for instance, use of nebulizer, flow calibration, etc.

We are investigating the matter further. However, in the meantime should you have any queries or require further information, please do not hesitate to contact me.

Yours sincerely

Steve Nixon
Director - Viamed Ltd.