

MHRA incident report number: **2012/001/018/401/002**

Dear Mr McIvor

I tried to contact you this morning by phone in order to discuss the above incident report; which we learned of following receipt of the message below via our web site:

Adrian Morgan
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Clinical Engineering
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Type: Technical

We have experienced an incident involving one of your Flowsensor A flow sensors fitted to a Draeger Evita XL ventilator. The sensor caught fire shortly after being fitted (new sensor). The MHRA have been informed as have Draeger. We are currently awaiting instruction from MHRA.

Obviously we are greatly concerned about this report and would like to investigate it straight away.

As far as we are aware there isn't anything in regard to the manufacturing materials that could cause this incident and we have never heard of such involving our sensors.

However, a risk could occur if a contaminated fuel source was introduced, say if the sensor was used immediately after being disinfected. It also has to be considered whether the patient circuit or ventilator 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...

We would like to tender our full co-operation in this matter, as it is in the interest of all parties to promptly identify the cause of the incident - whether it is due to parts, equipment or operational practice.

Kind regards

Steve Nixon
Director – Viamed Ltd.