

Telephone call to Mr Adrian Morgan 19/01/12 at 10:05

MHRA report number 2012/001/018/401/002

Sensor used on ICU, Mr Morgan thought that they purchased direct with us, but the I.D 477634 (lot 07-2011) shows the sensor was sold to Medical Physics/Clinical Engineering on the 16/09/11, invoice IN117596, customer ref. 200269473.

Mr Morgan says that one maybe both of the platinum wires have broken and the housing has suffered fire damage. He does not want to release the sensor; I asked if he could supply us with a picture of the sensor. In addition I asked if the sensor had been cleaned and he stated that the sensor had been used straight out of the box.

Date of the incident 13/01/12.

I advised Mr Morgan that we will contact the MHRA for instructions on how to proceed.

Viamed discussion.

Discussed with Ryan, decided to review Draeger Evita operating manual.

Fire hazard warnings found in the manual relating to cleaning the flow sensor, page 194 Instructions for Use Evita XL/Evita XL Neo SW 7.On

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Enquired if patient circuit had been cleaned prior to use, in view of WARNING in Draeger manual about possible fire hazard after flow sensor disinfection...

He says that the ventilator had been in use for 30 minutes. He did say that they had been using 100% oxygen, but he said that this shouldn't have been an issue during calibration.

Telephone call from Bernd Lindner 19/01/12 at 11:42

Conclusion: there must be a fuel source to cause this problem, which could happen with sensors from any manufacturer.

Telephone call to Mr Doug McIvor (MHRA) 19/01/12 11:48

No reply, left voicemail request from Mc McIvor to return the call.