Medical Device Incident Investigations: Recommendations

Flow Sensor – Evita XL – NeoFlow: Occlusion by degradation products

TGA reference: DIR 16049

The TGA has received a report that a NeoFlow flow sensor in a Draeger Evita XL ventilator was completely occluded with a blue gel-like substance resulting in the respiratory arrest of a patient.

Draeger Medical Australia has received five complaints over the last 10 years about a cyan colouring of the NeoFlow sensor, however this is the only report of a complete occlusion.

In this incident, the ventilator recorded the first of a series of warnings and alarms related to blocked tubes about 10 hours prior to the ventilator alarming "blocked tube alarm" and the respiratory arrest of the patient. The flow sensor had been in use for approximately nine days. The ventilator was checked and confirmed to have functioned and alarmed appropriately.

The manufacturer concluded the occlusion may have occurred if:

i. the flow sensor was not removed during nebulisation and thus drug residues were deposited inside the housing, or

ii. there was excessive secretion from the patient.

Both Draeger Medical Australia and the TGA have thoroughly investigated the material and believe it to be largely (aqueous) copper chloride with smaller amounts of nickel and copper-beryllium alloy compounds and traces of unknown organic compounds. The corrosive materials in the flow sensor caused a degradation of the connecting pins in the device. The resultant material is a metal-organic foam that can be seen as a blue/green gel inside the flow sensor.

If left to build up the compound can result in the flow sensor becoming completely occluded.

Draeger Medical Australia issued a Device Notice Safety Alert on 5 July 2007 to users of the device advising of the remote possibility that the flow sensor can become blocked with degradation products.

Draeger Medical Australia can be contacted on 1800 800 327, or at: Draeger Medical Australia Pty Ltd
PO Box 329
Mount Waverly VIC 3149

Recommended actions:
Ensure the Device Notice Safety Alert is distributed to doctors, neonatal intensive care nurses, respiratory therapists, and biomedical engineers as the TGA believes the consequence of a blockage may be fatal if the attending staff does not intervene promptly when the ventilator alarms.

Ensure current operating procedures are in accordance with the manufacturer's instructions for use. Should an alarm suggest airflow blockages, including high tidal volume, apnoea and tube blockage alarms, be sure to check the flow sensor. These alarm messages are outlined in the Evita XL instructions for use manual.

The Neoflow sensor is a reusable product. Therefore it is important that the instructions for use for reprocessing this device be strictly followed.

IV giving sets – Infusion of blood through giving sets that do not have a filter

The TGA has recently received a report raising concern over the practice of infusing blood using IV giving sets that do not contain a microfilter. The rationale given for this practice was:

i. IV giving sets with a filter are more expensive and hence some healthcare facilities have opted not to purchase these in order to prevent their excessive use for general IV fluid administration where filters are not required; and

ii. decreased awareness of the importance of using IV giving sets with filters when administering blood.

The Australian Red Cross Blood Service and the Australian and New Zealand Society of Blood Transfusion have both recommended that an IV giving set with a 170-200 micron filter be used when infusing blood.

It is important to use an IV giving set with a filter when transfusing blood to ensure that small blood particles which have the potential to cause injury, such as small clots which may be in the blood infusion, are not transmitted to the patient.

Recommendation
It is recommended that IV giving sets with a 170-200 micron filter are used when administering blood via intravenous infusion.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT
01/04/2007 to 30/06/2007
Total Number Received: 280
Total number of investigations completed: 238

Cause of Problem[1]

Component Failure	21
Contamination	10
Design	11
Electrical	16
Inadequate Instructions	3
Labelling	2
Maintenance	2
Manufacture	18
Material/Formulation Deficiency	12
Mechanical	20
Not Device Related	33
Other	26
Packaging/Sterility	2
Quality Assurance	6
Unknown	77
Wear/Deterioration	9

Effect

Death	9
Serious Injury	55
Temporary Injury	64
No Injury	110

Source Category

Medical Administrator	4
Specialist	13
Nurse	8
Blood Bank	1
Hospital Supply Service	16
Other	2
Biomed Engineer	5
Para Medical	1
Patient/user	22
Coroner	1

Result of Investigation

Bulletin Article	2
Company Warned	1
Compliance Testing	1
No Further Action	43
Not Investigated[2]	152
Other	7
Problem Not Confirmed	12
Product Improvement	13
Recall/Hazard Alert	7
Safety Alert	6
User Education	3

Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.

2. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are “Not Investigated” the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.