Medical Device Incident Investigations: Statistics and Recommendations

Safety Alert – Colleague Volumetric Infusion Pump 2M8151K

An incident investigation conducted by the manufacturer of the Colleague Volumetric Infusion Pump has revealed a problem of malfunction of the on/off circuit. The malfunction of the on/off circuit can occur if fluid enters the main body of the pump which, after long-term exposure, causes a short circuit. A short circuit may then cause unexpected 'power on' or 'power off' without a key press. This may occur with or without an alert or alarm sounding, and if it should occur during patient delivery, there is potential that delivery of therapy may be interrupted.

The fluid has most likely been entering the pump when it is being cleaned between uses or if there has been a significant spill of IV fluids onto the pump. Fluid enters the pump body and settles on the ribbon behind the keypad. The ribbon cable may degrade and short circuit if the exposure is prolonged.

Recommendation:

Baxter Healthcare, the sponsor of the pumps in Australia, has issued a Safety Alert. The Safety Alert advises that users of these devices or those who are assigned to clean these devices should follow the instructions for use, which state that the pump should be cleaned with a cloth dampened only with warm soapy water or other specified cleaning solutions. The pump should not be immersed or cleaned with an excessively wet cloth.

At the next service of these pumps, an insulator will be placed in the area of the ribbon cable to prevent the effect of fluid contacting the circuitry.

Gemstar Infusion Pump Administration Set

Gemstar infusion pump administration sets without an anti-siphon valve have not been available in Australia since 2001 due to problems of free flow with this type of set. Only sets with an anti-siphon valve have been available from Abbott for these pumps since then.

Since that measure was taken, there have been reports where the user has removed the anti-siphon valve to prime the line. The valves have not been subsequently replaced and when the administration set has been placed into the pump incorrectly, free flow has occurred. The problem occurs only with general purpose Gemstar administration sets. Abbott Gemstar patient controlled analgesia and epidural sets do not have a removable anti-siphon valve.

If the cassette in the administration set is not placed into the pump correctly, or if the cassette flow control switch is not set to STOP or OFF after priming, the patient may receive an overdose.

Recommendation:

Removing the anti-siphon valve for priming, or for any other reason should be avoided.

If the anti-siphon valve is removed, other checks should be used to prevent free-flow situations. These checks should include ensuring that the cassette flow control is set to stop or off, that the cassette has been correctly fitted and checking all of the connections and clamps during set up and prior to connecting to the patient.

Care should be taken to ensure that both the pump and the set instructions for use are followed at all times during setting up.

Glucoflex R test strips for checking blood glucose levels

Reflolux SIIM and II meters should be used with Glucoflex R test strips. The TGA has received notification from the product sponsor that some patients have been using the incorrect test strips for their blood glucose monitor. These patients had been using Betacheck, not Glucoflex R strips.

The confusion seems to have stemmed from changes to the ordering form used to order the test strips. The National Diabetes Services Scheme (NDSS) has made the changes to eliminate the confusion for patients and pharmacists about what test strips are required. The NDSS will also notify all Diabetes Australia State and Territory agents to alert them to the change to reinforce the need to follow instructions for use set out by the manufacturer of the monitors and test strips.

Recommendation:

Patients, prescribers and pharmacists should check that the appropriate test strip is supplied for the patient's blood glucose monitor.

Patients should follow the manufacturer's instructions for using and calibrating the monitor, especially when using a new packet of test strips. If the strips look or behave in an unusual way, patients should report the incident to a diabetes care professional, pharmacist or the TGA.

Substitution of Nitrous Oxide for Entonox

A patient who was in labour was transported to theatre to undergo a Caesarean Section. It was noticed in the operating theatre that the patient was being administered 100% nitrous oxide via mask instead of Entonox (a mixture of 50% nitrous oxide and 50% oxygen). The patient was exposed to nitrous oxide for approximately 10 minutes, breathing on the mask for up to 6 minutes, before the anaesthetist detected the substitution of gases. Fortunately, the patient did not suffer any ill effect.

This incident was caused by an unfortunate series of human errors and equipment fault that went undetected. The supplier delivered a D-size cylinder of 100% Nitrous Oxide in addition to the customary order of Entonox. Cylinders for both products are very similar in appearance. Nitrous Oxide is supplied in a blue cylinder while Entonox is colour-coded blue with white quadrants on the shoulder denoting oxygen. Both are labelled with the name of the gas or gas mixture. The Nitrous Oxide cylinder had been retrieved from the storeroom and attached to an Entonox regulator and patient mask. The indexing pin on the regulator that would prevent the inadvertent connection of the delivery unit to the wrong cylinder was missing.

All hospital ward staff who change the Entonox have now been advised of the incident and systems have been set in place to ensure they are aware of the difference between the two cylinders.

The supplier of the gas has been notified of the incident and will instruct its delivery contractors in the correct procedures to prevent incorrect supply of gases. The examination revealed that the regulator was manufactured in early 1970s. During the time of its use, the regulator was inspected and maintained by an independent contractor.

Recommendation:

Hospital staff using either Nitrous Oxide or Entonox should be aware of the similarity in the colour coding of the two gases. Checking of the product labels prior to administration of drugs is essential. All scheduled drugs should be given under medical supervision only.

Procedures should be established to minimise the possibility of selecting the wrong cylinder from storage. Cylinders and regulators should be handled carefully and in accordance with Occupational Health & Safety guidelines.

Regulators should be inspected and calibrated periodically by qualified service providers. Further inquiries may be directed to Gosia Pendel at BOC Gases Australia Limited on 02 8874 4741.

Peripherally Inserted Central (Venous) Catheters

The TGA has received reports from both Australia and New Zealand of serious adverse events associated with guide-wires used with Peripherally Inserted Central (venous) Catheters (PICCs).

These guide-wires are of slightly different design depending on the catheter, but most often consist of an outer coil of wire wrapped around and welded to a central core of wire at the proximal and distal ends.

The reports relate to the inadvertent cutting of the guide-wire while trimming the length of the catheter at the time of insertion, resulting in a piece of guide-wire remaining within the patient's circulatory system and requiring further intervention to retrieve it.

In one instance, it was noticed that the wire was difficult to withdraw. Once withdrawn, x-rays revealed that a section of the wire had separated and had been left in the pulmonary artery. In most other cases, inadvertent cutting of the guide-wire during shortening of the catheter caused it to unravel inside the patient when an attempt was made to remove the wire. In every case, the user noted that the wire

was somewhat difficult to withdraw.

Recommendation:

Shortening of the catheter should be avoided whenever possible. This eliminates the need for cutting and the incidence of accidentally cut guide-wires. The instructions for use of most PICCs caution against the inadvertent cutting of the guide-wire prior to insertion of the catheter.

If it is necessary to shorten the catheter, the catheter manufacturer's instructions for doing so should be carefully followed, taking precautions to ensure that the wire has not been inadvertently cut.

Recall for Product Correction of Ulco Anaesthetic Machine

The TGA has received several reports about an "oily substance" that has been found collecting inside the tubing found leading to the common gas outlet in Ulco Anaesthetic Machines. The substance has also been seen to collect in the tubing that carries gas to the back bar, and the tubing that connects the common gas outlet to the absorber. The problem has been detected in several machines at several hospitals.

The anaesthetic agents halothane, isoflurane and sevoflurane appear to "dissolve" part of the tubing (probably the plasticisers) leaving a similar oily substance and depleted and hardened tubing.

The TGA Laboratories analysed a sample of the tubing and some of the oily substance that had collected in a machine due to normal use. The infra red absorption spectrum (FTIR) of the inner surface of the tube was characteristic of PVC. The infra red absorption and the mass spectrum (GC/MS) of the oily substance was characteristic of di-2ethylhexylphthalate (DEHP), the most commonly used PVC plasticiser. Product literature for sevoflurane and isoflurane confirmed that PVC is in fact incompatible with these anaesthetic agents.

In further experiments conducted by the TGA, it was found that anaesthetic vapour swells the PVC to a great extent. The plasticiser is highly soluble in the anaesthetic agent, which causes it to leach out of the plastic.

There was some concern that the phenomenon had not been noticed despite many years of use. However, interviews with a biomedical engineer and a service technician have revealed that the hoses are regularly replaced "because of hardening". As the plasticiser leaches out, the tubing will gradually harden. Pooling of the DEHP inside the tubes is only the most extreme sign of the problem. The TGA has conducted rigidity tests on specimens of tubing returned from a Melbourne hospital. The rigidity of the specimens had more than doubled compared with new tubing.

It is difficult to determine how much of the material, if any, would have been transferred into a patient's lungs. However, it is much more likely that the DEHP would have been deposited in the absorber or some other part of the anaesthetic machine.

The toxicity of DEHP has received a lot of attention in the literature—the material is toxic to liver and kidney function particularly at high dose, and the material has also been found to be toxic to the reproductive organs of infant animals. Very little is known about the toxicity of this substance taken through the respiratory route.

Recommendation:

The TGA has recommended that Ulco contact all their customers advising them to inspect and change the tubing. The manufacturer has agreed to supply compatible replacement tubing. This constitutes a recall for product correction under the Uniform Recall Procedures, however it should be stressed that machines will not be taken out of service during the action.

The TGA has also contacted other suppliers of manufacturers of anaesthetic machines. As far as the TGA is aware, no other anaesthetic machine supplied in Australia has anaesthetic agent contacting components made of PVC.

The tubing in the anaesthetic machines should be checked for integrity and any signs of hardening or deterioration. At least one of the ends of the tube should be disconnected and swabbed inside to check for the presence of the plasticiser (oil). If oil or deterioration is found the tubing should be changed. In any event, the PVC tubing should be replaced with more compatible tubing when the machine is next due for service at the latest.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS)
STATISTICS REPORT: 01/01/2002 to 31/3/2002
Total Number Received: 125

Cause of Problem[1]	
Biocompatibility	17
Component failure	29
Contamination	4
Design	9
Diagnostic Inaccuracy	1
Electrical	1
Inadequate Instructions	1
Labelling	5
Maintenance	2
Manufacture	6
Material/Formulation Deficiency	16
Mechanical	5
Not Applicable- ADR	1
Not Device Related	21
Other	11
Packaging/Sterility	7
Quality Assurance	4
Unknown	8
Wear/Deterioration	1

Effect	
Death	8
No Injury	91
Serious Injury	7
Temporary Injury	19

Result of Investigation	
Bulletin Article	2
Company Warning	1
Compliance Testing	1
No Further Action	45
Not Investigated[2]	52
Other	4
Problem Not Confirmed	1
Product Improvement	8
Recall/Hazard Alert	7
Refer to GMP	4
Safety Alert	6
User Education	6

Source Category	
Medical Administrator	7
Specialist	6
General Practitioner	1
Coroner	6
Nurse	21
Blood Bank	9
Hospital Supply Service	22
Other	13
Patient/User	3
Sponsor	25
Overseas Advice	2
Biomed Engineer	10

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.