

Medical Device Incident Investigations: Recommendations

Safety Alert—Delivery of 100% nitrous oxide by Ulco Elite 615 anaesthetic machine

The TGA recently received an adverse event report from an anaesthetist regarding the potentially lethal problem of delivery of 100% nitrous oxide by Ulco Elite 615 anaesthetic machine. Both the reporter and the manufacturer cited that another similar incident, which had not been reported to the TGA, occurred at a different hospital early in 2005. In both incidents a restriction or obstruction to fresh gas flow resulted in delivering a hypoxic gas mixture in the patient circuit. The O₂ fail alarm and the anti-hypoxic device failed to trigger in both cases.

According to the manufacturer, the Ulco Anti-Hypoxic Device requires the second-stage N₂O regulator to be set at a pressure 30kPa above the second-stage O₂ regulator. Therefore, when an obstruction in the fresh gas hose occurs, the higher pressure N₂O is able to 'force' its way through at a higher rate than the O₂. In both incidents, this restriction or obstruction was caused when the fresh gas hoses (which ran from the Selectatec backbar to the patient block under the working tray area) had been kinked and dislodged by equipment such as printers and other modules placed under the table on the top of the drawers. The manufacturer stated that the Elite 615 machines were not originally designed for the mounting of printers or other tall modules under the work table area.

To mitigate the risk of recurrence the manufacturer has inserted an information leaflet in Elite 615 service kits that describes the nature of the problems likely to be experienced when the fresh gas hose is kinked, and a number of recommendations to reduce the likelihood of occurrence. Furthermore, Ulco will offer a retrofit kit that will enable concerned users to sheath the fresh gas hose in solid PVC tubing, further reducing the likelihood of hose kinking.

Recommended actions

- If there are some Ulco Elite 615 anaesthetic machines in your hospital, please bring this Safety Alert to the attention of hospital biomedical engineers and any staff members who operate and maintain the machines.
- Ulco registered service agencies and hospital biomedical engineering departments who maintain Ulco Elite 615 anaesthetic machines should have received an information leaflet about the nature of this problem and recommendations to reduce its likelihood. If you have not received this information leaflet, please contact Ulco Engineering Pty Ltd.
- The Elite 615 machines were not originally designed for the mounting of printers or other tall modules on the top of the drawers; these types of components should not be placed there.
- Sheathing the fresh gas hose in solid PVC tubing will further reduce the likelihood of hose kinking. PVC fresh gas hose sheaths are available from Ulco Engineering Pty Ltd.
- Sometimes even simple modifications can lead to unforeseen problems. The manufacturer(s) of the original equipment should be consulted before any modifications to the original design and intention are carried out. This will ensure that the modifications are not likely to compromise the safety or performance of the medical device.

Safety Alert—Rate responsive pacemakers and patient monitoring systems

The TGA recently received a device incident report in which a patient, fitted with a minute ventilation, rate responsive pacemaker, exhibited high pacing rates when connected to an ECG machine. Pacing rates reverted to normal when the patient was disconnected from the ECG.

Minute ventilation, rate responsive pacemakers vary the pacing rate in response to changes in tidal volume and respiration rate. A small, sub-threshold current is passed between the pacing electrode

and the device 'can' and this allows variations in transthoracic impedance which occur as a consequence of breathing movements to be measured. The pacemaker can provide an appropriate rate increase or decrease response based on changes in tidal volume and respiration rate.

When the rate modulation function in these devices is turned ON, it is possible that interaction with other external signal-generating sources, such as TENS machines, interferential therapy units, or impedance-based respiration monitoring systems such as are commonly found in patient monitoring systems, can interfere with the correct operation of the pacemaker.

Recommendation

Before a patient is monitored or given treatment using ECG, patient monitoring systems, TENS machines, or any other equipment likely to generate external signal, check whether the patient is fitted with this type of pacemaker. If so consult with either the hospital Cardiology Department or Pacemaker Clinic before proceeding.

Adverse events associated with improper or absent preparation of the chest area prior to defibrillation

Issue

The TGA regularly receives reports from users and sponsors about adverse events where a patient has not been able to be defibrillated effectively due to improper or absent preparation of the chest. The reports state that:

- the patient's hair caught fire or
- the operators were unable to get an ECG trace or defibrillate the person because they had too much hair or oil or perspiration.

Defibrillator pads need to adhere to as much of the patient's skin as possible so that a successful defibrillation is achieved. The instructions for use on all defibrillators state that the user must ensure that the patient's skin is clean and dry. The user should remove ointments, moisture and excess chest hair.

Recommendation

A razor and/or clippers should be placed with the defibrillator or in the resuscitation trolley. Hospital and ambulance checklists should include a razor and this, along with the rest of the equipment, should be checked and signed off as per the facility or network's protocol.

Before applying the defibrillator pads, wipe the skin with a dry cloth and, if possible, shave the chest hair. (**Note: shaving is contra-indicated if the patient is going to be paced or if other procedures are going to be carried out. In these cases, the patient's chest hair should be clipped with scissors or an electric razor.**)

Ensure that Gel electrodes contact as much skin as possible and be careful not to trap air between the gel and the skin.

Do not conduct chest compressions over the electrodes as this may damage the electrodes.

Coring of rubber bungs by IV giving sets

The TGA recently received a small number of reports of rubber pieces being found in the filter of IV giving sets following puncture by these sets through a rubber bung.

The concern is that if a user does not use an IV giving set with a filter there is a possibility that rubber may find its way into the patient via the IV line.

Recommendation

The manufacturers of the medicine containers are investigating whether the rubber from which the bung is made can be improved to avoid coring.

As a precaution, IV giving sets with a filter should always be used when infusing fluids from containers that require piecing through a rubber bung.

Urinary catheter balloon size and filling capacity

The TGA recently received reports of urinary catheters falling out because the catheter balloon was not completely filled. The reports indicate that the balloon was filled with 5mls of water. This is the stated balloon capacity on the catheter's packaging. The non-return valve stated 10mls but because the catheterisation took place in theatres the outer packaging was read by the scout nurse and a 5ml syringe and water were supplied to the scrub staff who filled the balloon without paying attention to the non-return valve.

The cause appears to be a discrepancy between the catheter's packaging label and the information printed on the non-return valve of the inflation tube on the catheter.

Urinary catheter packaging labels have the balloon capacity stated but do not always have the total fluid volume required to fill the balloon and inflation tubing. This information is usually on the non-return valve of the inflation tube.

The standard (AS/NZS2696:1996) used by most catheter manufacturers states that "for catheters with balloons the rated capacity in millilitres expressed as mL, ml, cm3, or cc" shall be on the unit package and the catheter. The definition of rated capacity is the capacity of the balloon or that capacity plus an additional volume designated by the manufacturer. In other words, the greater capacity on the unit label or the catheter is the correct rated capacity and the correct quantity of water that should be used.

Recommendation

Many urinary catheter manufacturers make a distinction between 'rated balloon capacity' and fill volume. The TGA will continue to work with manufacturers to establish clearer labelling and instruction practices for urinary catheters. In the meantime, users should check the volume stated on the unit label and the non-return valve. If different, the fill volume is usually the greater of the two values.

Unexpected tilting of the Australian Medical Couches OMNI 510 Procedure Couch

The TGA recently received a device incident report in which a patient fell off an OMNI 510 Procedure Couch while being examined. The bed unexpectedly tilted into the Trendelenburg position causing the patient to slide off, head first.

When the examination began the patient was lying on the bed which was at normal working height and as the patient leant onto the head of the bed, it tilted causing the bed to move into the Trendelenburg position.

When the bed is in a low position the possibility of tilting is minimal. However, when the bed is raised slightly and force is exerted on the head of the bed, the linkages, which are part of the bed's control mechanism, may allow the bed to freely tilt into the Trendelenburg position. There is no safety mechanism to stop the bed from accidentally tilting into the Trendelenburg position.

The manufacturer of this bed has stated that the Trendelenburg position option can be removed from the bed. The manufacturer no longer supplies this examination couch.

Recommendation

If your OMNI 510 examination couch has the Trendelenburg position option and you would like it removed please contact Australian Medical Couches on 03 9376 0060. If you choose to retain this option, the TGA advises extreme caution when using the couch at a raised height and that the patient should also be secured to the couch.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/07/2006 to 30/09/2006

Total Number Received: 288

Cause of Problem ¹		Effect		Result of Investigation	
Biocompatibility	7	Death	19	Bulletin Article	5
Component Failure	41	Serious Injury	40	Company Warned	3
Contamination	1	Temporary Injury	97	No Further Action	74
Design	9	No Injury	132	Not Investigated 3	118
Diagnostic Inaccuracy	1			Other	9
Electrical	2	Source Category		Problem Not Confirmed	35
Inadequate Instructions	3	Medical Administrator	10	Product Improvement	27
Labelling	1	Specialist	8	Recall/Hazard Alert	5
Maintenance	5	Nurse	16	Refer to GMP	1
Manufacture	21	Blood Bank	4	Refer to surveillance	2
Material/Formulation Deficiency	9	Hospital Supply Service	11	Safety Alert	8
Mechanical	18	Other	19	User Education	14
Not Applicable—ADR ²	7	Sponsor	178		
Not Device Related	40	Overseas Advice	12		
Other	24	Biomed Engineer	17		
Packaging/Sterility	3	Para Medical	2		
Quality Assurance	8	Patient/user	8		
Unknown	91	Dentist	0		
Wear/Deterioration	6	Coroner	2		

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. ADR stands for Australian Device Regulatory [Action]. These devices are not on the Australian Register of Therapeutic Goods (ARTG) and companies are notified and/or warned that they must place the device on the ARTG prior to further supply.
3. 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.