

# Medical Device Incident Investigations: Recommendations

## Don't throw away your samples!!

Too often in our process of investigating adverse events, the samples are not available to assist in our research as to why this event occurred. The need to view the complaint samples whether it is the packaging or the actual medical device can be critical in determining the cause and often the remedy to an adverse event.

The device involved, and its packaging if possible, should be retained so that a more comprehensive investigation of the event can occur.

Please keep your devices until the TGA has received your report and indicated whether we need to inspect the device prior to sending it to the manufacturer.

Some instructions for sending samples are listed below:

1. Clean the device as much as possible without destroying any evidence that you feel contributed to the adverse event.
2. All devices should be double-packaged in plastic bags designed for transporting bio-hazardous objects. The outer package must be clearly labelled with the contents and warnings if the device is contaminated.
3. If the device has sharp edges or components such as suture needles, please pack these items into a sealed plastic container in addition to the plastic bags.

Further information can be found on the TGA website <<http://www.tga.gov.au/problem/iris/devices-testing.htm>>.

## Battery in a patient monitor caused a fire

The TGA recently received an Incident Report about a fire occurring in a multi-parameter patient monitor. The fire caused the evacuation of the health facility.

The manufacturer's investigation into the adverse event identified that the root cause of the fire was associated with the battery supplied by a third party. The battery did not have the necessary safety features and continued to receive AC power resulting in continued overheating of the battery.

Batteries supplied by the monitor manufacturer for use in these monitors are specifically-designed batteries to prevent these types of incidents from occurring. Due to safety concerns, the manufacturer of the monitor involved in the incident has advised that the use of batteries supplied by third parties may void the warranty.

This manufacturer has also modified the design of all their new monitors to ensure that third party batteries are no longer able to be inserted into their monitors.

The TGA strongly recommends that the manufacturer's instructions should be followed in relation to the choice and use of batteries in all patient monitors.

## Safety Alert: Incorrect loading of the Baxter Flo-Gard IV administration set can cause blood loss

The TGA has received an incident report regarding the incorrect loading of a Baxter Flo-Gard IV administration set which caused blood to be pumped from the patient into the IV solution bag. This event occurred at night but fortunately the patient awoke and discovered the problem.

The TGA tested a pump and infusion set and was able to confirm the reported problem. The sets used in both the incident and the TGA's testing were standard Baxter soft tubing administration sets FNC1165 (see picture) with a slide clamp loading feature. The set is loaded into the infusion pump starting with inserting the slide clamp into the slide clamp slot. The IV line tubing is loaded through the pump mechanism tubing guides (refer to Figure 4 copied from Flo-Gard 6201 operator's manual). However, in the report to the TGA the user had inserted the slide clamp upside down which lead to the patient-end of the tubing being fed through the pump's mechanism guide therefore drawing blood from the patient, through the pump, and subsequently into the medication bag. There is no alarm to indicate that fluid is being drawn from the patient and into the infusion bag.

FNC1165



The TGA has reviewed the Baxter Flo-Gard 6201 Operation Manual and considers it has adequate instructions in regards to loading the administration set. A warning and direction label has been applied to the door of the pump to remind users of the correct way of loading the administration set. Furthermore, information supplied with the pump instructs the user to observe the drip chamber for at least 10 drops after starting the infusion. Trained personnel should be able to load the tubing correctly by following the instructions for use.

The TGA and Baxter Healthcare have not received any other reports of this type in the past two years. However, the ECRI database reported that this problem had been indicated in several Medical Device Reporting (MDR) reports from the FDA since 1992; but, no patient injuries had been reported<sup>1</sup>.

These pumps are being used in the home and this report was from a home user. Home users are generally less experienced in the use of infusion pumps. The TGA considers that the instructions for use and warning labels for the Baxter Flo-Gard 6201 may be difficult for users with limited training to interpret and the home environment is also devoid of the safety and support systems found in hospital.

The TGA believes that the consequence of blood loss could threaten patients' lives. The TGA has confirmed with Baxter that this problem can occur with the Baxter Flo-Gard 6301 pump as it uses the same administration set with the same

mechanism for loading administration set as the Flo-Gard 6201.

The result of this investigation has been that Baxter has issued a safety alert to warn home use patients of this problem. Baxter recommend in this safety alert that home use patients use an administration set containing a non-return valve. The use of this type of administration set is that an upstream occlusion will occur preventing backflow of blood from the patient and activating the pump alarm.

## Recommended actions

- Please bring this Safety Alert to the attention of all Baxter Flo-Gard 6201 and 6301 users, particularly home users.
- Please refer to the Operator's Manual and labels that are provided with each device for a complete list of all warnings and precautions associated with use of these devices.
- Follow the instructions for use for loading the set into the pump including observing flow from the drip chamber after starting the pump.

The TGA encourages users to report any advert events regarding medical devices to the TGA and the manufacturer to help to prevent further incidents.

## Reference

1. "General-purpose infusion pumps" *Health Devices* 1997;26(2) 50-75.

## Understanding medical device package labelling symbol

Since the implementation of regulation of single use medical devices in 2003 in Australia, end users of these devices have become more aware of device package labelling and the meaning of those labels. Copies of the *Instructions For Use* are not always available with every device as often there is one copy per box which is discarded when the box is opened. This means that the packaging label is a very important source of information to the user about the product.

The Incident Report Investigation Scheme (IRIS) has received problem reports and calls from healthcare professionals and end users of medical devices seeking clarification on the meaning and interpretation of symbols used on labelling instructions for use for medical devices.

The symbol  is an international standardised symbol listed in ISO15223:2007 "Medical Devices – symbols to be used with medical device labels, labelling and information to be supplied" and means DO NOT REUSE. SINGLE USE is interpreted to mean the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient. Some manufacturers will use this symbol in combination with the words "SINGLE PATIENT USE". This is interpreted to mean more than one episode of use of a medical device on the same patient. The device may undergo some form of reprocessing between each use in accordance with the manufacturer's instructions for reuse on the same patient.

The TGA recommends;

1. End users refer to the IFU available with these types of medical devices,
2. Contact the TGA if they have any further enquiries on this subject OR access the TGA website [www.tga.gov.au/medicaldevices/sud](http://www.tga.gov.au/medicaldevices/sud).
3. Report through the TGA's IRIS any adverse events or problems associated with the labelling and/or use of single use medical devices.

## Maintenance of hospital beds—An important issue in preventing injury to patients and staff

**Issue:** A health worker has sustained a serious injury, amputation of a finger, while operating an electric bed. This incident occurred while two healthcare workers were tending a patient back to bed.

The brake pedal of the bed had loosened and disengaged while the bed was lowered. The weight of the bed was temporarily supported by a retaining washer on the lower edge of the bed elevation mechanism and the out-of-position brake pedal. This was mistakenly believed to be the lowest position of the bed.

The bed was held up for a short time and at the same moment one of the healthcare workers was trying to insert a foot stool under the foot-end of the bed with their hand placed in the gap between the bed and the foot stool.

The bed suddenly dropped from a height of about 3cm and the healthcare worker's ring finger was amputated.

**Background:** An investigation was conducted by the manufacturer who found:

- The bed's brake was left in a steering position; according to the instruction manual it should always be in the locked position when the bed is positioned or unattended.
- A loosened brake pedal might indicate there is either a lack of 'defective equipment' reporting and response process, or an ineffective routine maintenance program.
- The maintenance schedule does not appear to have occurred as there was no record of this bed being checked in more than twelve months.

## Recommendations

- Always consult the manufacturer's instructions prior to operating the bed; this is best covered at orientation for all new employees.
- Ensure problems with bed function are reported and acted on promptly.
- Ensure all beds are inspected annually and an effective maintenance schedule is conducted by an appropriately-qualified technician. Annual inspections should include checking of all fasteners to ensure proper fit, position, and tightness.
- Ensure the brakes are fully engaged prior to raising or lowering the bed.
- Avoid placing foot stools or other obstacles beneath the bed's corner tube as this can create a dangerous pinch point.

## Marshall Torrens electrically operated hospital beds— Patient safety issues

**Issue:** The South Australian Department of Health and the Therapeutic Goods Administration have received reports of incidents where the backrest and wheel mounting supports of Marshall Torrens hospital beds had either broken or had been damaged. Sudden failure of the bed, particularly at the backrest mounting support could result in patient injury.

The South Australian Department of Health has also identified that the bed design presents an unacceptable risk of patient entrapment and is advising hospitals within South Australia accordingly.

**Background:** Marshall Torrens electrically operated beds were manufactured by Marshall Furniture in South Australia in the late 1990s. This company no longer exists and the TGA has been unable to determine the extent of supply but believes the beds may be isolated to South Australia. It is known that many beds are still in use.

Investigation of these reports have identified that the beds are subject to:

- Metal fatigue at the backrest actuator's mounting point on the backrest, and
- Weld cracks around the wheel mounting supports.

### Recommendation

South Australian Department of Health has recommended that in relation to the structural issues:

- Users of Marshall Torrens beds conduct, if not already doing so, a rigorous inspection program of all aspects of bed safety and operation. In view of reports received, particular attention should be given to the structural integrity of the backrest actuator mounting point and the bed caster mountings.
- Where evidence of fatigue is found, the bed should be either taken out of service and replaced, or repairs be carried out to strengthen the area around the backrest mounting or the backrest be replaced with a strengthened design.
- Although it may be possible to strengthen the area around the backrest mounting, the thickness of the material is such that it may allow transfer of stress and, as a result, metal fatigue may recur at a point beyond the repaired area. Therefore, regular ongoing inspection of the beds is recommended, regardless of whether they have been previously repaired.
- Hospitals that decide to repair or replace the backrest frame support or to replace the backrest frame with a strengthened design need to be aware that any such modification will infer manufacturer status on the hospital along with the associated product liabilities.

For detailed advice please contact South Australian Department of Health:

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- If you are not in South Australia and have some of these beds please report this to the TGA and follow the instructions above.

## Misconnection of electrosurgical bipolar electrodes

The problem of misconnection of Electrosurgical Bipolar Electrodes in the surgical environment continues to be challenging.

The TGA has recently received a report of an experienced operating theatre staff member misconnecting bipolar electrodes into an electrosurgical unit (ESU) monopolar terminals. A literature review has revealed that serious adverse events associated with electrosurgical misconnection have also occurred abroad. The misconnection occurs when the two connectors of the bipolar electrode are accidentally plugged into two of the three monopolar terminals. It appears that this potential for misconnection exists with all brands of electrosurgical bipolar electrodes that have banana-type plugs mounted on flexible cables (see Figure 1).

When misconnected, the bipolar electrode may cause the ESU to inadvertently activate without operator initiation or control. If the monopolar power output has been programmed into the ESU (eg been left at its previous setting), the patient or operator can suffer serious burns or electric shock.

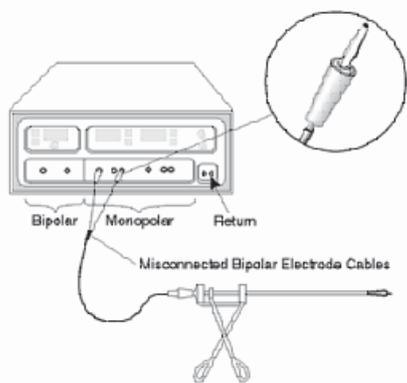


Figure 1. Flexible bipolar electrode cables can allow misconnection of bipolar leads into the monopolar jacks, resulting in serious patient injury.

The activation mechanism for the hazardous monopolar current was described by Reeter in 1990: "The closed forceps short-circuit the ESU's switching circuit and turn on the monopolar current."

ECRI also published an article on bipolar electrode misconnection in 1993:

*If the bipolar electrode leads are plugged into the active monopolar jack and either one of the monopolar switching jacks, the ESU will be inadvertently activated when the tips of the bipolar forceps either 1) touch and short the leads together or 2) span the tissue with low enough impedance to permit activation.*

Once activated the bipolar electrode will continue to hazardously discharge electricity until the electrode is unplugged or the ESU is turned off. Serious harm may occur during the time taken to deactivate the electrode.

The International Electrotechnical Commission (IEC) parent standard medical electrical device safety requires all patient circuit connections to be so designed that they cannot be hazardously connected to wrong outlets. Similarly, the Australian national parent standard for medical electrical device safety requires the design and construction of bipolar electrodes to prohibit misconnection:

### 56.3 Connections – General

#### a) Construction of connectors

*Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented were a SAFETY HAZARD may be caused.*

Recent amendments have been implemented in the IEC 60601-2-2 Part 2-2: Particular requirements for the safety of high frequency surgical equipment, which states:

#### \*46.104

*a) ACTIVE OUTPUT TERMINALS on HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT shall differ in configuration sufficiently such that MONOPOLAR ACTIVE ACCESSORIES, NEUTRAL ELECTRODES and BIPOLAR ACTIVE ACCESSORIES cannot be improperly connected. See Annex AA*

*b) ACTIVE CONNECTORS having more than one pin shall have fixed pin spacing. "Flying leads" are prohibited.*

*c) ACTIVE CONNECTORS having no more than a single pin need not be investigated.*

It is hoped in the future that manufacturers will now take on this information and this problem should be lessened.

In the meantime the following recommendations are made for operating theatres.

### Recommendations

1. Alert staff to the hazards of misconnecting the electrosurgical bipolar electrode to the ESU monopolar terminals. The greatest risk is presented to the patient and operator who may be exposed to uncontrolled electrosurgical current at monopolar power levels.
2. Ensure that the bipolar electrode is connected to the proper ESU terminals before operation.
3. Consider using bipolar electrodes that are designed to prevent misconnection.
4. Implement procedures that require the monopolar electrode to be plugged in before the return electrode (eg thigh pad) is plugged into the ESU.
5. Implement procedures that require all ESU output/operating modes to be set to their minimum until the surgeon is ready to proceed in that mode. An output mode should remain at its minimum setting throughout an operating procedure until that mode is required. If an output mode is no longer required during a procedure it should be set to its minimum output.

### References

1. A.K. Retter, "Bipolar Forceps Misconnection Hazardous" *OR Manager* Feb 1990; 6(2):13.
2. Anonymous, "Misconnection of Bipolar Electrosurgical Electrodes" *Health Devices* Jan 1995; 24(1):34-5.
3. IEC 60601.1.0: 1998 *Medical electrical equipment – Part 1: General requirements for the safety – Parent Standard*. The 'particular' standard does not specifically refer to bipolar electrodes requiring design and construction that prevents misconnection: IEC 60601.2.2: 1999 *Medical electrical equipment – Part 2: Particular requirements for the safety of high-frequency surgical equipment*.
4. AS 3200.1.0: 1998 *Medical electrical equipment – Part 1: General requirements for the safety – Parent Standard*, Clause 56.3 a), p. 89. AS 3200 series is based on the IEC 60601 series.
5. IEC 60601-2-2 Fourth edition 2006-07 *Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment*, pgs 59 .

## Medical Device Incident Report Investigation Scheme (IRIS) Statistics Report 01/04/2008 to 30/06/2008

Number of device incident reports received: 279

The full IRIS statistics report for the period 01/04/2008 to 30/06/2008 is available on the TGA website <<http://www.tga.gov.au/problem/iris/statistics.htm>>.