



Medical Devices Safety Update

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Battery management a growing issue

The ever-increasing number of battery-using devices in health settings highlights the need for the health sector to minimise risks by implementing protocols and procedures for battery management.

The health sector reflects our wider society in general in that over time it has placed ever greater reliance on electronic devices. Many of these electronic devices utilise batteries of various types and in many health applications – for example, pacemakers, defibrillators and portable ventilators – batteries play a critical role in device function.

In addition almost all facilities use a range of uninterruptible power supplies (UPS) that rely on batteries.

The TGA has received more than 50 adverse event reports over the past 10 years involving deaths or serious injuries where a battery-related problem was listed as a potential contributing factor.

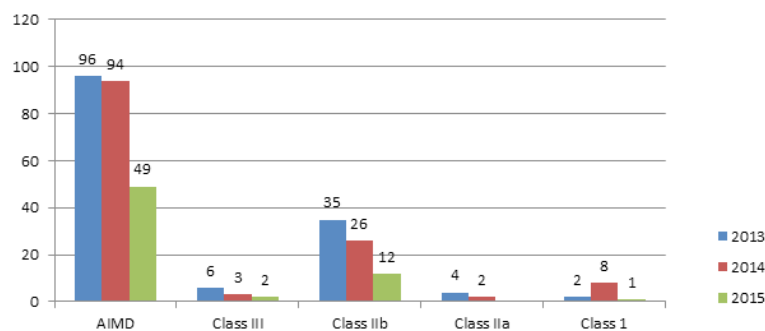
Battery problems have affected a wide variety of devices across all classes – life-sustaining, therapeutic,

monitoring and imaging. In recent years the TGA has issued safety alerts discussing battery-related issues for a wide range of devices including [cardiac defibrillators](#), [implantable pulse generators](#), [ventricular assist devices](#) and [pacemakers](#).

Reported problems

The classes of medical devices are determined by their level of risk. Active Implantable Medical Devices (AIMDs) and Class III devices are classified as the highest risk levels. Class I is the lowest risk level. See Part 1, Section 4 of the [Australian regulatory guidelines for medical devices](#) for further details of device classification.

Figure 1: All battery-related reports Jan 2013 – Oct 2015 by device category



Class I: Thermometers, Batteries, Patient Lifters, and similar (lowest risk)
Class IIa: Light source, bed, and similar
Class IIb: Telemetry, automatic external defibrillators, infusion pumps, and similar
Class III: Intra-aortic balloon pumps, and similar
AIMD: Implantable pacemakers, defibrillators and ventricular assist devices (highest risk)
 (Note: this is not a complete list of classes or devices)

Medical Devices Safety Update is the medical devices safety bulletin of the Therapeutic Goods Administration (TGA)

In total there were 345 battery-related reports from January 2013 to October 2015, with AIMDs dominating the battery failure reports. The batteries on these devices are generally non-rechargeable and replacement would require surgery.

Investigations usually reveal battery depletion is due to excess current drain (low circuit impedances, high output settings and the like) and not generally battery failure.

In addition to battery problems with AIMDs, there have been reports for other devices such as infusion pumps, insulin pumps, patient monitors and vision systems. A wide variety of devices and battery types are represented (see Figure 2).

The most common kinds of battery failures are for rechargeable batteries that fail to charge, fail to hold a charge, or are not inserted correctly.

Users should follow the battery replacement and maintenance recommendations set out by the original equipment manufacturer so that both the

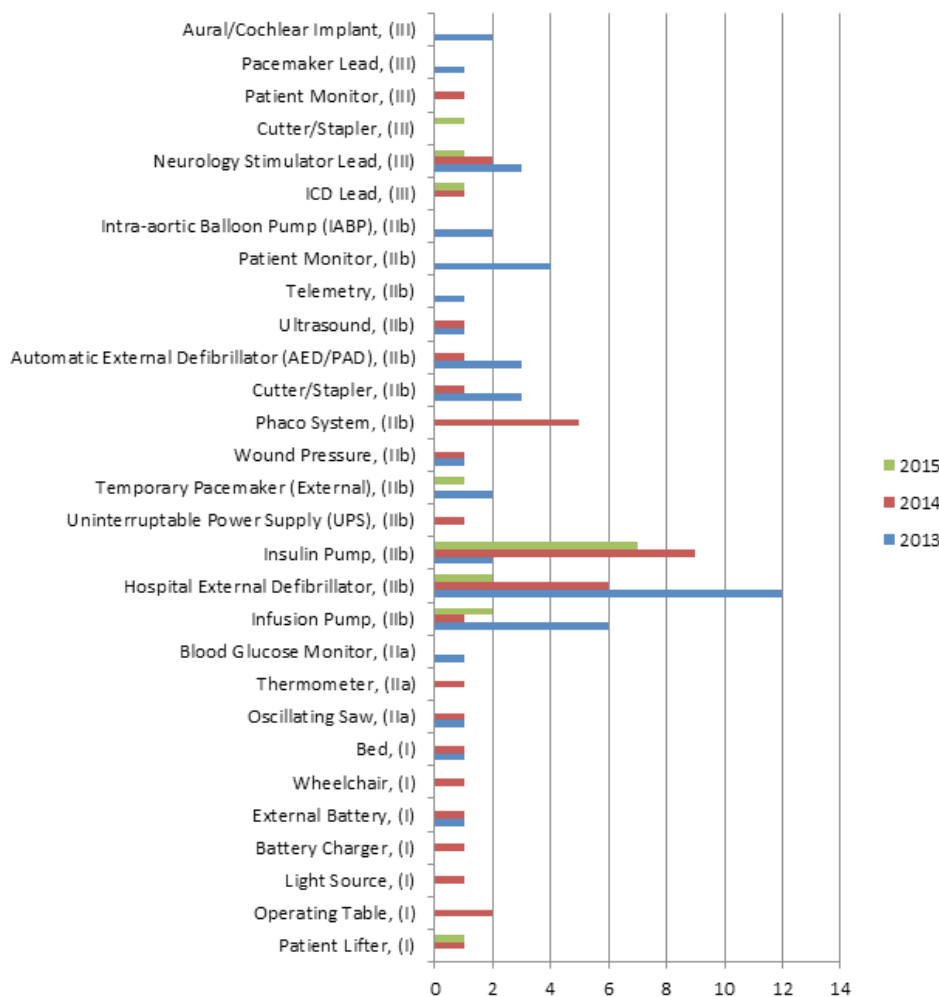
device and battery performance will be as expected and certified by the manufacturer.

Develop protocols and procedures

Health facilities and those responsible for maintenance of devices containing batteries should ensure that suitable protocols and procedures are developed to optimise battery management and reduce risks. Factors that these protocols should consider include:

- ensuring staff are familiar with and follow the manufacturer’s instructions
- using the best quality battery cells available
- developing a planned replacement schedule
- routine retirement of old batteries
- ensuring charging regimes suit each battery type
- setting up routine battery testing timetables
- incorporating recycling options.

Figure 2: All battery-related device problem reports January 2013 – October 2015 (excluding AIMDs)



Safety alerts issued for two knee implants

The sponsors of two tibial components have issued safety alerts for their products after they were identified in the Australian Orthopaedic Association National Joint Replacement Registry 2015 annual reports as having higher-than-expected revision rates.

Following the TGA's investigation of implants identified in the [annual reports](#) as having higher-than-expected revision rates, the alerts were sent to implanting surgeons to provide more information about the specific circumstances in which these rates occurred and to provide advice to reduce the risks.

Tibial components are used in conjunction with other components to form complete systems used in total knee replacements.

The safety alerts related to the ACS fixed-bearing cementless porous coated tibial component (sponsored by Oceania Orthopaedics and distributed in September) and the Scorpio Series 7000 cementless beaded tibial components (sponsored by Stryker and distributed in December), both of which are used in total knee replacements. Both safety alerts were distributed after consultation with the TGA.

ACS fixed-bearing cementless porous coated tibial component

Oceania's investigation isolated the trend to Australian centres where cementless implants had not been previously utilised.

There were two main factors underlying the higher-than-expected revision rates:

- A series of patella-only and total knee implant revisions took place at one centre after a particular technique – the mobile-bearing tibia-first surgical technique – was utilised. Oceania's safety alert highlighted that when the tibia-first technique is used with a mobile-bearing knee implant, it is essential to make sure that the knee is 'balanced' (the alignment checked) before femoral resection. If the knee is not balanced first, misalignment of the femoral component is possible when referencing the resected tibia for femoral rotation. Symptoms of patella pain, patella erosion or pain may occur and lead to early revision.

- The investigation identified that the cementless tibial implant was used in a number of cases where a cemented implant would have been preferable. Oceania advised that patient selection and the intraoperative assessment of bone quality and stability throughout the process are critical elements of successful cementless knee replacement surgery. To help mitigate this issue Oceania has engaged a centre of excellence to aid in the training of surgeons who are considering using cementless implants. All new, first-time users of the ACS fixed-bearing cementless porous coated tibial component will be asked to undertake the training before they use this implant.

For more detailed information, contact Oceania Orthopaedics on 1300 828 618.

Scorpio Series 7000 tibial components

Stryker's safety alert addressed the higher-than-expected revision rate of Series 7000 cementless tibial components when used in combination with Scorpio NRG PS cementless femoral components.

Stryker's investigation, which included a case-by-case review of surgical notes and x-rays, found:

- The stability of the 7125 cementless tibial component may have been adversely affected by inadequate host bone quality in a proportion of cases.
- The higher revision with the 7145 series is not device-related.
- The 7515 series is performing as expected.
- Used individually, Scorpio NRG PS cementless femoral components and Series 7000 cementless tibial components have a record of good performance and revision rates that are in line or lower than comparable implants.

Stryker's safety alert highlighted that careful patient selection for cementless knee arthroplasty was a critical part of the pre-operative evaluation.

The Instructions for Use for Scorpio Series 7000 tibial components contraindicate implantation of these devices in patients with bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.

For more detailed information telephone Todd Pironis at Stryker Australia on 02 9467 1000.

IUCDs and uterine perforation

While it is known that uterine perforation is a rare adverse event associated with the use of intrauterine contraceptive devices, a recent European study has found that risk is increased for lactating women and during the first 36 weeks postpartum.

The European Active Surveillance Study was a large prospective, comparative, non-interventional cohort study assessing users of intrauterine contraceptive device (IUCD), including copper IUCDs and levonorgestrel IUCDs, who had a primary outcome of uterine perforation.¹

Copper IUCDs are regulated by the TGA as medical devices, while Mirena, which contains the active pharmacological agent levonorgestrel, is regulated as a medicine. While the risk of uterine perforation associated with all types of IUCDs is low, the European Active Surveillance Study identified an increased risk of uterine perforation in lactating women and during the first 36 weeks postpartum for all such devices.

In response to the study, the TGA undertook a post-market review of copper IUCDs.

European Active Surveillance Study

Patients for the European Active Surveillance Study were recruited from 2006 to 2013 with a sample size of 61,448 IUCD users – 54% of women used a copper IUCD and 46% used a levonorgestrel IUCD.

The study included women who were postpartum and who were breastfeeding at the time of IUCD insertion; these groups of women have largely been excluded from previous studies.

There were 61 perforations with a levonorgestrel IUCD and 20 with a copper IUCD. First-time users

of levonorgestrel IUCDs had a slightly higher rate of perforation than first-time copper IUCD users. Both breastfeeding at the time of insertion and insertion up to 36 weeks after delivery were independently associated with an increased risk of uterine perforation.

While the background rate of uterine perforation associated with IUCDs was low, there was a six-fold increase in perforation risk (relative risk 6.1; 95% confidence interval 3.6 - 10.1) with breastfeeding regardless of the interval since the last delivery.

There was no statistically significant difference between copper IUCDs and levonorgestrel IUCDs.

Changes to Instructions for Use and Product Information in Australia

For copper IUCDs, the TT380 and LOAD 375 devices, both sponsored by Medical Industries Australia, are in the process of having their Instructions for Use updated to include the relevant information from the European study. Another copper IUCD, Multiload sponsored by Merck Sharp & Dohme (Australia), has recently been withdrawn from the market, with the last device supplied in April 2015.

The [Mirena Product Information](#) has been updated to include information regarding the increased uterine perforation risk for lactating women and during the first 36 weeks postpartum. Additionally, the [PI](#) now advises that there is also an increased risk for women with a fixed, retroverted uterus.

REFERENCE

1. Heinemann K, Reed S, Moehner S, Minh TD. [Risk of uterine perforation with levonorgestrel-releasing and copper intrauterine devices in the European Active Surveillance Study on Intrauterine Devices](#). Contraception; 2015.

Recent safety alerts

Below are TGA safety alerts relating to medical devices published since the last edition of *Medical Devices Safety Update*.

[Anatomic Locked Plating System](#): Hazard alert - risk of soft tissue irritation

[Silimed medical devices](#): Update - Products suspended from ARTG until quality standards met

[InSync III cardiac resynchronisation therapy pacemakers](#): Hazard alert - potential battery issues

[Optisure dual coil defibrillation leads](#): Hazard alert - potential for loss of therapy due to lead insulation damage

[EndoBarrier duodenal-jejunal bypass liner](#): Hazard alert - risk of liver abscess

inSite program extends to Sydney

Following the success of a pilot project in the ACT, the TGA's IRIS inSite adverse event reporting program will expand into northern Sydney.

The TGA will deliver education and support services to the Northern Sydney Local Health District (NSLHD) in 2016 as the IRIS inSite program expands beyond the pilot phase.

The IRIS inSite project works closely with health facilities to educate health professionals about medical device adverse event reporting.

The pilot project demonstrated a positive impact on the frequency, rate and quality of reports received and consequently TGA's ability to safeguard the use of therapeutic goods in Australia.

The NSLHD includes large health facilities, such as Royal North Shore Hospital (RNSH) and smaller public hospitals.

Private hospitals including those that are co-located with public hospitals in this local area health network will be approached to participate in the inSite program in mid-2016.

The IRIS inSite trial took place at [three hospitals in the ACT](#) (an additional site was subsequently added to the two mentioned in the linked article) and there was a significant and sustained improvement in reporting from all participating sites.

The three hospitals combined had reported a total of 38 medical device adverse events in 2013. In 2015 they had already reported 99 adverse events by the end of October.

The 2015 reports also included a greater percentage relating to the prevention of issues, rather than reporting incidents which had already occurred and resulted in negative outcomes for patients or staff.

For the latest information from the TGA, subscribe to the TGA Safety information email list via the TGA website

For correspondence or further information about Medical Devices Safety Update, contact the TGA's Medical Devices Branch at iris@tga.gov.au or 1800 809 361

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What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies

- device interactions
- user/systemic errors

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at www.tga.gov.au (click 'Report a problem')
- **by emailing** iris@tga.gov.au
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713

For more information about reporting, visit www.tga.gov.au or contact the TGA's Medical Devices Branch on 1800 809 361.

DISCLAIMER

The Medical Devices Safety Update (MDSU) is aimed at health professionals and is intended to provide practical information on medical devices safety, including emerging safety issues. The information in the MDSU is necessarily general and is not intended to be a substitute for a health professional's judgment in each case, taking into account the individual circumstances of their patients. Reasonable care has been taken to ensure that the information is accurate and complete at the time of publication. The Therapeutic Goods Administration gives no warranty that the information in this document is accurate or complete, and does not accept liability for any injury, loss or damage whatsoever, due to negligence or otherwise, arising from the use of or reliance on the information provided in this document.

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