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Safety Notice

SN:006/06

Therapeutic Goods Administration (TGA) Recalls

27 October 2006

Distributed to:

- Chief Executives
- Directors of Clinical Operations
- Directors of Clinical Governance

Action required by:

- Directors of Clinical Governance

We recommend you also inform:

- Clinical Product Managers
- Directors of Nursing
- Directors of Radiology
- Maintenance

Quality and Safety Branch

NSW Department of Health

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The established process for TGA medical device recalls/product corrections is for the manufacturer/sponsor to dispatch letters to the relevant service providers within two working days of the recall date. If affected, your health service will have received a letter from the manufacturer/sponsor advising of the recall. **TGA Class I** defects are potentially life threatening or could cause serious risk to health. **Class II** defects could cause illness or mistreatment, but are not Class I.

This Safety Notice is provided to reinforce the TGA process. It contains TGA Class I and selected Class II medical device recalls/product corrections for your implementation, if relevant.

Class I**Balt Extrusion Goldballoons (Reference: RN-2006-0707)****Recall date: 18 October 2006****Issue:** The Goldballoon device may deflate after implantation.**Further information:** N. Stenning & Co Pty Ltd, Ms Vicki Parker 1800 225 828**Class II****P3700 Affinity Three Birthing Beds (Reference: RN-2006-0683)**

Beds distributed after October 2000 and equipped with the 12 VAC Accessory outlet option.

Code: ARTG No. 58615**Recall date: 3 October 2006****Issue:** A potential overheating hazard may exist affecting the low-voltage transformer for the accessory outlet. It is possible for the thigh section to overrun its stops during articulation and come into contact with a wire connected to the low voltage transformer. Overtime, it is possible to wear through the insulation causing a short that can lead to overheating of the transformer.**Further information:** Hill-Rom Australia Pty Ltd, Technical Support (02) 8814 3000**Philips Multi-Measurement Server (MMS) (Reference: RN-2006-0665)****Code:** Model M3001A, M1020B Pulse Oximetry Module Philips FAST SpO2 and M1020B Pulse Oximetry Module Nellcor® OxiMax® Compatible which is used with various Philips patient monitors**Recall date: 12 October 2006****Issue:** In rare cases, a pulse Oximetry (SpO2) saturation level of 100% may be displayed for an extended period of time even though a sensor is not attached to a patient.**Further information:** Philips Electronics Australia, Customer Care Centre 1800 251 400**Identity Pacemaker (Reference:RN-2006-0716)****Code:** Models SR 5172, DR 5370 and XL DR 5376, ARTG number 82180**Recall date: 16 Oct 2006****Issue:** A programmer software anomaly has been discovered that can lead to incorrect reporting of battery voltage, expected battery longevity and Elective Replacement Indicator (ERI) status in these three models of pacemakers. The anomaly does not affect the actual battery voltage, longevity OR functionality but could result in inaccurate reporting of the status of these measured data parameters.**Further information:** St Jude Medical Australia Pty Ltd, Ross Sutherland 02 9427 5100**Suggested Actions by Area Health Services**

1. Determine if this Safety Notice is relevant for your Area Health Service
2. Ensure that this Safety Notice is distributed to all relevant stakeholders
3. Ensure that relevant areas have received letters from sponsor of implementation strategies necessary.