

# Safety Notice

Safety Notice No: 2/10 page 1 of 8  
Issued by SA Department of Health, Safety and Quality Unit  
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A patient **Safety Notice** strongly advises the implementation of particular recommendation or solutions to improve quality and safety.

## We recommend you inform:

- Supply Department
- Biomedical Engineering
- Safety and Quality Unit
- Clinical Departmental Managers

## Contact details:

T: (08)8226 6188  
F: (08)8226 0725

## Therapeutic Goods Administration (TGA) Recalls

### Summary for February 2010

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.

Class I – are potentially life-threatening or could cause a serious risk to health.

Class II – could cause illness or mistreatment, but are not Class I.

Class III – may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

Class I & II recalls are considered to be safety related recalls.

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

Persons receiving this notice should ***NOT*** take any further action unless the affected goods are supplied to/in use in their health service

#### FOR SA HEALTH STAFF ONLY

Due date for response to the Department of Health is  
**1 April 2010.**



# Safety Notice

**Safety Notice No: 2/10 page 2 of 8**

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## Alerts

### **Selected models of Medtronic implantable pacemakers EnRhythm Model P1501DR (ARTG number 119251) and EnRhythm MRI SureScan Model EDMR01**

ARTG NUMBER: 162632  
REFERENCE: RC-2010-RN-00136-3  
DATE AGREED: 1/02/2010  
SPONSOR: Medtronic Australasia Pty Ltd  
PHONE: 03 8851 1022 – Richard Lauder  
REASON: Two battery issues have been identified  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

### **Tec 6 plus Desflurane vaporiser**

ARTG NUMBER: 93955  
REFERENCE: RC-2010-RN-00112-3  
DATE AGREED: 05/02/10  
COMPANY: GE Healthcare Aust Pty Ltd  
PHONE: Service and Support Centre 1300 722 229  
REASON: the product is not defective and is not being recalled – Reminder is being issued regarding several key instructions to be followed in the operation of the product.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

### **Bedfont NOxBox Inhaled Nitric Oxide Therapy Monitor**

ARTG NUMBER: 133965  
REFERENCE: RC-2010-RN-00102-3  
DATE AGREED: 01/02/10  
COMPANY: Air-Met Scientific Pty Ltd  
REASON: This product is not defective and is not being recalled. Bedfont Scientific Pty Ltd are unable to guarantee to support the delivery and servicing of these monitors beyond an approximately 5 year lifespan.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

**February 2010**



# Safety Notice

**Safety Notice No: 2/10 page 3 of 8**

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## Alerts (cont)

### **Epicor Ultrawand LP handheld ablation device**

ARTG NUMBER: 160367  
REFERENCE: RC-2009-RN-00937-3  
DATE AGREED: 16/11/2009  
COMPANY: St Jude Medical Australia Pty Ltd  
REASON: Refer to attached letter.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

### **Stryker Stretcher Model 1001 manufactured prior to 1998**

ARTG NUMBER: 138521  
REFERENCE: RC-2009-RN-00921-3  
DATE AGREED: 16/11/2009  
COMPANY: Stryker Australia Pty Ltd  
REASON: Refer to attached letter.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

### **Disposable Rigid Sigmoidoscopes and Anoscopes System**

REFERENCE: RC-2009-RN-01032-3  
DATE AGREED: 18/12/2009  
COMPANY: Welch Allyn Australia Pty Limited  
REASON: Refer to attached letter.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites



# Safety Notice

**Safety Notice No: 2/10 page 4 of 8**

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## Class I Recalls

### **Allura Xper Systems and Allura Integris Systems with Vlara Generator (X-ray systems)**

ARTG NUMBER: 98560  
REFERENCE: RC-2010-RN-00075-3  
DATE AGREED: 27/01/10  
COMPANY: Philips Electronics Australia Ltd  
PHONE: 1800 251 400 - Philips Customer Care Centre  
REASON: Due to intermittent shortcuts inside the Velara Generator, a system lock-up might occur that can only be resolved by a warm or cold System restart. In exceptional circumstances the Generator is damaged and the system cannot be restarted.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Royal Adelaide Hospital, Ashford Community Hospital, Calvary Wakefield Hospital.

### **Philips Switched Reusable Internal Defibrillation Paddles. Paddles Manufactured From 1 SEP - 30 DEC 08. PRODUCT NO: MA741A; M4742A; M4743A; AND M4744A**

ARTG NUMBER: 95861  
REFERENCE: RC-2010-RN-00096-3  
DATE AGREED: 29/01/10  
COMPANY: Philips Electronics Australia Ltd  
PHONE: 1800 251 400 - Philips Customer Care Centre  
REASON: Paddle shock switch may fail to actuate and delay or prevent delivery of defibrillation therapy.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
The Queen Elizabeth Hospital

### **Philips HeartStart FR2+ and FRx Automated external defibrillators (AEDs) Selected units manufactured in October 2009**

ARTG NUMBER: 92346  
REFERENCE: RC-2009-RN-00915-3  
DATE AGREED: 12/11/2009  
COMANY: Philips Electronics Australia Ltd  
PHONE: 1800 251 400 - Philips Customer Care  
REASON: These devices contain a capacitor that may not meet performance standards.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

**February 2010**



# Safety Notice

**Safety Notice No: 2/10 page 5 of 8**

Issued by SA Department of Health, Safety and Quality Unit  
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## Class II Recalls

### **Femoral Sponges. Catalogue No: 0206715000. All lots from 15 July 2004**

ARTG NUMBER: 139937  
REFERENCE: RC-2010-RN-00089-3  
DATE AGREED: 29/01/10  
COMPANY: Stryker Australia  
PHONE: 1800 803 601 - Lachlan McKenzie  
REASON: Stryker instruments has identified the potential for a breach in sterility to the sterile packaged femoral sponge.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Calvary Hospital, Modbury Hospital, Mount Gambier Health Service

### **Hill-Rom Affinity Four Birthing Bed. Serial number range H331AA4785 to J170AA9123. Production Dates 27 Nov 06 - 18 Jun 08**

ARTG NUMBER: 151145  
REFERENCE: RC-2010-RN-00094-3  
DATE AGREED: 02/02/10  
COMPANY: Medcraft Hill-Rom Australia Pty Ltd  
PHONE: 02 9562 0932 - Caleb Wong  
REASON: Problem with brakes not holding or locking properly.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Child Youth & Women's Health Service, Burnside War Memorial Hospital, Home Health Equipment

### **COULTER PrepPlus & COULTER PrepPlus 2, PART NUMBERS 286600 AND 378600**

REFERENCE: RC-2010-RN-00118-3  
DATE AGREED: 09/02/2010  
COMPANY: Beckman Coulter Australia Pty Ltd  
PHONE: 1800 060 881 – Technical Centre  
REASON: Potential dilution of reagent vials loaded on the PrepPlus or PrepPlus2 systems.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
SA Pathology



# Safety Notice

**Safety Notice No: 2/10 page 6 of 8**

Issued by SA Department of Health, Safety and Quality Unit  
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## Class II Recalls (cont)

### **Peloris Rapid Tissue Processor Part no. 26.001**

REFERENCE: RC-2010-RN-00122-3  
DATE AGREED: 09/02/2010  
COMPANY: Leica Biosystems Melbourne Pty Ltd  
PHONE: 03 - 92117400 - Andrew Ellis  
REASON: Reports have been received of losses of biopsy tissue. A software update is available to minimize events that could lead to tissue damage during processing.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Adelaide Pathology Partners, Flinders Medical Centre, Forensic Science SA, Lyell McEwin Hospital, The Queen Elizabeth Hospital, Royal Adelaide Hospital, Women's and Children's Hospital

### **Omega IV and Omega V tables on Advantx-E and on Innova 2000, 2100IQ, 3100, 3100IQ, 4100, 4100IQ, 2121IQ and 3131IQ cardiovascular X-ray systems**

ARTG NUMBER: 93871  
REFERENCE: RC-2009-RN-00930-3  
DATE AGREED: 19/11/2009  
COMPANY: GE Healthcare Australia Pty Ltd  
PHONE: 1800 659 465 - GE Customer Care  
REASON: Due to potential weakness of some table rotational brakes, an unintended table rotation may occur while the table is locked.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Flinders Private Hospital, Royal Adelaide Hospital

### **GE Centricity PACS RA1000 Workstations (Picture archiving and communication system) Software Versions: 1.0x, 2.0x, 2.1x and 3.x**

ARTG NUMBER: 115596  
REFERENCE: RC-2009-RN-00928-3  
DATE AGREED: 11/11/2009  
COMPANY: GE Healthcare Australia Pty Ltd  
PHONE: 1800 659 465 - GE Customer Care Centre  
REASON: Various issues with workstation software may lead to a potential patient's misdiagnosis, or delay in treatment.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Flinders Medical Centre, Repatriation General Hospital

**February 2010**



# Safety Notice

**Safety Notice No: 2/10 page 7 of 8**

Issued by SA Department of Health, Safety and Quality Unit  
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## Class II Recalls (cont)

**AMO Tecnis 1-Piece Intraocular Lens. Product code ZCB00. All units with expiration / use by dates (YYYY-MM): 2011-06, 2011-07, 2011-08 & 2011-09  
Selected units with expiration / use by dates (YYYY-MM): 2011-05 & 2011-10 supplied prior to or on 31 October 2009**

ARTG NUMBER: 147537  
REFERENCE: RC-2009-RN-00906-3  
DATE AGREED: 6/11/2009  
COMPANY: Advanced Medical Optics Australia Pty Ltd  
PHONE: 1800 266 111 – AMO Customer Service Representative  
REASON: Reports that the haptics of some Tecnis 1-Piece Intraocular Lenses (IOLs) have adhered to the lens optic after delivery  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
The Queen Elizabeth Hospital, Gawler Health Service, St Andrews Hospital

## Broselow/Hinkle™ Paediatric Emergency System Intraosseous Modules

ARTG NUMBER: 58851  
REFERENCE: RC-2009-RN-00950-3  
DATE AGREED: 19/11/2009  
COMPANY: Device Technologies Australia Pty Ltd  
PHONE: 02 9972 8326 - Gary Todd  
REASON: Broselow/Hinkle™ Intraosseous Module, which is part of the Broselow/Hinkle™ Paediatric Emergency System, contains a 15G Intraosseous Needle that is not compatible with the IV Extension set that is provided in the module.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Renmark Paringa District Hospital



# Safety Notice

**Safety Notice No: 2/10 page 8 of 8**

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## Class III Recalls

### **Cable Diath Valleylab REM - 25 - 3508M (Diathermy Cables)**

**Product Code: 1330250180 Lot Number: 709886**

ARTG NUMBER: 141669

REFERENCE: RC-2009-RN-00971-3

DATE AGREED: 24/11/2009

COMPANY: Unomedical Pty Limited

PHONE: 02 9979 0846 - Andrew Smith

REASON: A single lot of Diathermy cables has been mis-labelled. The outer cartons and product pouches are labelled as CABLE-3508M but the cable inside is 3405M.

SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Royal Adelaide Hospital