

# Safety Notice

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Issued by SA Department of Health, Safety and Quality Unit  
www.safetyandquality.sa.gov.au



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) Alerts & Recalls

### Summary for March 2010

The established process for TGA medical device alerts, recalls and 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.

The aim of the Safety Notice is to inform health services about potential safety and quality issues requiring risk assessment at the local level to determine appropriate action(s) regarding any identified problems.

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

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

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

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

Class I recall – considered to be safety related recalls.

Class II recall – considered to be safety related recalls.

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  
**29 April 2010**



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## Alert

### **HomeChoice Automated PD System and HomeChoice PRO Automated PD System Product Code: R5C8320**

ARTG NUMBER: 129906  
REFERENCE: RC-2010-RN-00220-3  
DATE AGREED: 5/03/2010  
COMPANY: Baxter Healthcare Pty Ltd  
REASON: refer to attached letter  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

## Class I Recalls

nil

## Class II Recalls

### **Siemens Sonoline and Acuson Antares 4.0 and 5.0 systems and Acuson S2000 systems (These are general purpose ultrasound systems but have a cardiac capacity)**

REFERENCE: RC-2010-RN-00180-3  
DATE AGREED: 24/02/2010  
COMPANY: Siemens Ltd  
PHONE: 1800 227 587 - John Selakovic  
REASON: A software defect has been identified that could affect results when the product is used in a cardiac environment.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

### **Various differential blood cell counters**

### **COULTER LH 500 Analysers, COULTER LH 750 Analysers, COULTER LH 780 Analysers, COULTER GEN\*S Analysers, UniCel DxH 800 Coulter Cellular Analysis System**

REFERENCE: RC-2010-RN-00183-3  
DATE AGREED: 26/02/2010  
SPONSOR: Beckman Coulter Australia Pty Ltd  
PHONE: 1800 060 881 - Technical Centre  
REASON: Several software issues identified.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Flinders Medical Centre, Women's and Children's Hospital.

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## Class II Recalls (cont)

### **Innova 2100, 3100 and 4100 cardiovascular x-ray imaging systems Units distributed from March 2009 to February 2010 (cabinet model number 2335139-8)**

ARTG NUMBER: 93871  
REFERENCE: RC-2010-RN-00185-3  
DATE AGREED: 25/02/2010  
COMPANY: GE Healthcare Australia Pty Ltd  
PHONE: 1800 659465 - GE Customer Care  
REASON: Potential software failure  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Flinders Private Hospital

### **C.A.T.S. Auto Transfusion System Disposable Sets (AT1 disposable sets for the C.A.T.S. Auto Transfusion machines) Article number 9005101; Batch YGT031**

ARTG NUMBER: 126399  
REFERENCE: RC-2010-RN-00198-3  
DATE AGREED: 1/03/2010  
COMPANY: Fresenius Kabi Australia Pty Limited  
PHONE: 02 9391 5555- Fresenius Kabi Australia Medical Affairs  
REASON: Some complaints in which the C.A.T.S machine stops after priming and displays the alarm "Alarm Blood Flow" before initiating the transfusion procedure.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Royal Adelaide Hospital

### **GE OEC 9800 Mobile X-ray System**

ARTG NUMBER: 132698  
REFERENCE: RC-2010-RN-00211-3  
DATE AGREED: 2/03/2010  
COMPANY: GE Healthcare Australia Pty Ltd  
PHONE: 1800 659 465 - Customer Care Centre  
REASON: If the unit is powered down or shut off while the system is actively working to save or retrieve data to or from the internal hard drive, there is an increase in the potential safety issues identified, specifically, System No Boot, System Slow to Boot, Patient Data Loss and Patient Data Mix.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Repatriation General Hospital

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## Class II Recalls (cont)

### **14.8 Volt Lithium Ion Battery for use with the Philips HeartStart MRx Monitor/Defibrillator Product Number M3538A**

ARTG number 5661  
REFERENCE: RC-2010-RN-00223-3  
ATE AGREED: 5/03/2010  
COMPANY: Philips Electronics Australia Ltd  
PHONE: 1800 251 400 - Philips Customer Care  
REASON: Batteries older than 2 years which are subject to continuous use have a higher potential for intermittent electrical contact, which may contribute to an interruption in monitoring or therapy if the monitor/defibrillator is operating on battery power.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
All sites

### **Dimension Clinical Chemistry System - Lipase (LIP) Flex reagent cartridges (DF55A)**

**Lots: DE0320, FC0306, GB0342, EA0334, FB0278, DA0293, GB0286, FA0355, EA0362 and EB0362**

REFERENCE: RC-2010-RN-00240-3  
DATE AGREED: 12/03/2010  
COMPANY: Siemens Healthcare Diagnostics Pty Ltd  
PHONE: 02 9491 5360 - Mia Huymans  
REASON: Internal testing of the lots has shown upward shifts in QC and patient samples of up to 20%. The observed shifts can be seen as soon as two hours post hydration of the reagent wells.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Ashford Hospital, Gribbles Pathology.

### **UniCel DxH 800 Coulter Cellular Analysis System, Software Revision 1.1.2.0**

REFERENCE: RC-2010-RN-00257-3  
DATE AGREED: 16/03/2010  
COMPANY: Beckman Coulter Australia Pty Ltd  
PHONE: 1800 060 881 - Customer Support Centre  
REASON: Beckman Coulter has confirmed 4 issues for this device which are software-related.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Women's and Children's Hospital

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## Class II Recalls (cont)

**Siemens Advia Centaur Software Version 4.0  
Advia Centaur XP Software Version 6.0.  
(Immunoassay systems. In vitro diagnostic medical device - IVD)**

REFERENCE: RC-2010-RN-00259-3  
DATE AGREED: 16/03/2010  
COMPANY: Siemens Healthcare Diagnostics Pty Ltd  
PHONE: 1800 358 030 - Technical Support Centre  
REASON: These systems may exhibit event messages 700 00 01 and 700 00 02, which requires the systems to be rebooted on specific event dates  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
SA Pathology

## Class III Recalls

**Note: This recall extends a previous recall by Unomedical (TGA Ref: RC-2009-RN-00971-3)**

**Cable Diath Valleylab REM - 25 - 3508M (Diathermy Cables) Product Code: 3508M  
Lot Numbers: 568784, 621143, 621453, 621608, 622510, 622891, 624125, 705817, 706708,  
707056, 711299, 712552**

ARTG NUMBER: 141669  
REFERENCE: RC-2010-RN-00189-3  
DATE AGREED: 1/03/2010  
COMPANY: Unomedical Pty Limited  
PHONE: 02 9979 0846 - Andrew Smith  
REASON: Multiple lots of Diathermy Cables have potentially been mislabelled during production. 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.

**Chiron RIBA HCV 3.0 SIA  
(an in vitro diagnostic medical device used for blood donor screening)  
Product Code -930600  
Lots -YA1209, YA1691, YA1758, YA1804, 98290 and 98743**

ARTG NUMBER: 57040  
REFERENCE: RC-2010-RN-00228-3  
DATE AGREED: 12/03/2010  
COMPANY: Ortho-Clinical Diagnostics  
PHONE: 02 9815 3902 - Alexandra MacTavish  
REASON: There is an increased potential for false positive results.  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
SA Pathology

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## Class III Recalls (cont)

**KODAK T-MAT G/RA Film Emulsion 835 Roll 021 (24 x 30cm);  
Catalogue Number – 1510023, Lot - 835-021**

ARTG NUMBER: 136109  
REFERENCE: RC-2010-RN-00270-3  
DATE AGREED: 18/03/2010  
COMPANY: Carestream Health Australia Pty Ltd  
PHONE: 03 9274 3832 - Peter Rady  
REASON: A batch of T-MAT L/RA general radiography films have been incorrectly packed in T-MAT G/RA boxes  
SITES AFFECTED: (Only those sites listed are required take appropriate action)  
Benson Radiology

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