

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 May 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
24th June 2010



Government
of South Australia
SA Health

May 2010



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Alert

SYNGO imaging with version line VB2, VB30, VB35 in combination with a RIS

REFERENCE: RC-2010-RN-00415-3
DATE AGREED: 13/05/2010
COMPANY: Siemens Ltd
REASON: Potential safety issues related to incorrect UIDs (Unique Identifier) being added to the wrong patient.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

Inion CPS Biodegradable Fixation System Inion CPS Baby Biodegradable Fixation System

ARTG NUMBER: 154546
REFERENCE: RC-2010-RN-00429-3
DATE AGREED: 3/05/2010
COMPANY: Danex Medical Pty Ltd
REASON: Inadequacies in the instructions with respect to strength retention and maximum immersion time of plates/meshes in the water bath was not defined.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

Single Use Laryngoscope Blades

ARTG NUMBER: 161995
REFERENCE: RC-2010-RN-00444-3
DATE AGREED: 14/05/2010
COMPANY: Koala Medical Pty Ltd
REASON: New instructions have been issued concerning the fastening of the single use blade onto Laryngoscope handles prior to intubation.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

Revitan Disassembly Instruments 0100409801 & 0100409803 Located in Instrument tray 1CL02017252

ARTG NUMBER: 117920
REFERENCE: RC-2010-RN-00491-3
DATE AGREED: 14/05/2010
COMPANY: Zimmer Pty Ltd
REASON: The disassembly instrument and the threaded rod can seize if the prescribed maintenance as per the instructions is not followed.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

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Alert (Cont)

Various ICD and CRT-D Devices

REFERENCE: RC-2010-RN-00445-3
DATE AGREED: 6/05/2010
COMPANY: Medtronic Australasia Pty Ltd
PHONE: 02 9857 9000 Richard Lauder
REASON: Under specific conditions it is possible all subsequent high voltage therapies will experience prolonged charge time or loss of high voltage therapy.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
Flinders Medical Centre, Lyell McEwin Health Service, The Queen Elizabeth Hospital, Royal Adelaide Hospital, Ashford Hospital, Calvary Wakefield Hospital, Flinders Private Hospital, St Andrews Hospital

Device	Model	ARTG #
Consulta CRT-D	D234TRK	154089
Secura DR	D234DRG	154091
Secura VR	D234VRC	154090
Concerto II CRT-D	D294TRK	162425
Virtuoso II DR	D294DRG	162426
Virtuoso II VR	D294VRC	162427
Maximo II CRT-D	284TRK	154092
Maximo II DR	D284DRG	154094
Maximo II VR	284VRC	154093

Autoclave Camera Tray, Bio-absorbable Tray Base, Dilator Sterilisation Tray, Conquest Sterilisation Tray.

ARTG NUMBER: 140639
REFERENCE: RC-2010-RN-00501-3
DATE AGREED: 24/05/2010
COMPANY: Stryker Australia Pty Ltd
REASON: Updated instructions to address a potential lack of clarity in the sterilisation parameters.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites



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Class I Recalls

CPR Meters (HeartStart MRx ALS monitor) used with HeartStart MRx Monitor/Defibrillators

REFERENCE: RC-2010-RN-00458-3
DATE AGREED: 7/05/2010
COMPANY: Philips Electronics Australia Ltd
PHONE: 0418 272 708 - Michael Vogel
REASON: The force measurement sensor on the CPR meter can gradually lose sensitivity with use, thus providing users with inaccurate feedback on CPR compression.

SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

Serial Numbers:		
US00535663	US00538340	S00538341
US00538359	US00538361	S00538364
US00538373	US00538374	S00538376
US00538670	US00538874	

Selected HeartStart FR2+ automated external defibrillators (AEDs)

Model numbers M3860A, M3861A, M3840A, and M3841A

Manufactured by Philips and distributed between May 2007 and May 2010

Selected serial numbers only* (see attached list)

ARTG NUMBER: 92346
REFERENCE: RC-2010-RN-00519-3
DATE AGREED: 25/05/2010
COMPANY: Philips Electronics Australia Ltd
PHONE: 0418 272 708 - Michael Vogel
REASON: The recalled units may contain a component called a voltage detector from lots that have a higher than expected failure rate. Failure of the voltage detector can cause the AED battery to drain more rapidly than normal or to render the AED unusable.

SITES AFFECTED: (Only those sites listed are required take appropriate action)
Lyell McEwin Health Service, Calvary Hospital

GE RESPONDER – Automated External Defibrillators (AED) Models 2019189 and 2023440 Item No: 2023440-031 Serial No: 901785

ARTG NUMBER: 99183
REFERENCE: RC-2010-RN-00428-3
DATE AGREED: 6/05/2010
COMPANY: GE Healthcare Australia Pty Ltd
PHONE: 1300 722 229 - National Service & Support Centre
REASON: The daily/weekly/monthly self tests performed by the affected devices' software to ensure proper functioning, may not detect defects in certain electronic components that can lead to device failure.

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

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Class II Recalls

VICRYL Rapide Sutures Various lots and product numbers (see attached table)

ARTG NUMBER: 135005
REFERENCE: RC-2010-RN-00407-3
DATE AGREED: 27/04/2010
COMPANY: Johnson & Johnson Medical Pty Ltd
REASON: The packaging of all suture lots produced during May-June 2007 may be defective.
PHONE: 1800 257 210 - Brendan McClure
SITES AFFECTED: (Only those sites listed are required take appropriate action).
All sites

ADVIA Centaur Systems Calibrator A for FT4 Value Assignment Lots 068 & 069 An *in vitro* diagnostic medical device (IVD)

REFERENCE: RC-2010-RN-00465-3
DATE AGREED: 10/05/2010
COMPANY: Siemens Healthcare Diagnostics Pty Ltd
PHONE: 08 9241 4496 Vince Chiera
REASON: Use of these calibrator lots may result in low recovery of Quality Control material and patient samples. Shows a negative bias of up to 10%.
SITES AFFECTED: (Only those sites listed are required take appropriate action).
SA Pathology, Gribbles Pathology.

O-ARM Imaging System - Mobile View Station

ARTG NUMBER: 135566
REFERENCE: RC-2010-RN-00456-3
DATE AGREED: 7/05/2010
COMPANY: Medtronic Australasia Pty Ltd
PHONE: 02 9857 9381 - Rachel Patrick
REASON: A faulty component connection that handles the image data transmission between the O-ARM Imaging System stand and the Mobile Viewing Station during use of the 2D continuous fluoroscopy has the potential to cause the real time image display to refresh at a rate that is slower than the specified 30 frames per second.
SITES AFFECTED: (Only those sites listed are required take appropriate action).
Flinders Medical Centre

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Class II Recalls (Cont)

Feeding Tube FG 6 with X-Ray Line

ARTG NUMBER: 134000
REFERENCE: RC-2010-RN-00473-3
DATE AGREED: 10/05/2010
COMPANY: Unomedical Pty Limited
PHONE: 1800 803 987 - Customer Service
REASON: Instances of leaking have been observed between luer connector and the tube when fluid is passed through the tube.
SITES AFFECTED: (Only those sites listed are required take appropriate action).
All sites

Product Description	Product Code	Lot Number
Feeding Tube FG 6 x 40 cm with X-Ray Line	234.06.040	1034002, 1034277
Feeding Tube FG 6 x 60 cm with X-Ray Line	234.06.061	1033924
Feeding Tube FG 6 x 100 cm with X-Ray Line	234.06.100	1033866, 1034810

Cincinnati Sub-Zero (CSZ) Blanketrol II Model 222R Serial Numbers 963-12876 through 093-19768; and Cincinnati Sub-Zero (CSZ) Blanketrol III Model 233 Serial Numbers 062-3-00031 through 094-3-01183 (used in the treatment of hypo/hyperthermia)

ARTG NUMBER: 135609
REFERENCE: RC-2010-RN-00440-3
DATE AGREED: 17/05/2010
COMPANY: Medtel Pty Ltd
PHONE: 02 9413 6284 - Michael Ross
REASON: Potential for an electrical short due to water leak from the hose connections.
SITES AFFECTED: (Only those sites listed are required take appropriate action).
Children Youth and Women's Health Service



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Class II Recalls (Cont)

Maquet/Datascope's Intra-Aortic Balloon Pump Part Number: 0998-003013-55
Serial numbers: SA122359C8 & SA122375C8

ARTG NUMBER: 118266
REFERENCE: RC-2010-RN-00507-3
DATE AGREED: 18/05/2010
COMPANY: Maquet Australia Pty Ltd
PHONE: 02 9680 2518 - Neville Motley
REASON: The Intra-Aortic Balloon Pumps (IABP) manufactured with the display controller assembly date code 08_05 may exhibit display distortion, "pixeling" and blanking. Although the IABP continues to deliver therapy to the patient, these issues cause the user to be unable to read the information that is being displayed.

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

Innova 2000 Cardiovascular X-ray Imaging Systems

ARTG NUMBER: 93871
REFERENCE: RC-2010-RN-00517-3
DATE AGREED: 25/05/2010
COMPANY: GE Healthcare Australia Pty Ltd
PHONE: 1800 659 465 - GE Customer Care
REASON: A potential Source to Image Distance (SID) failure could occur on the Innova 2000 systems and may result in loss of x-ray generation.

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