



May 2009

A patient **Safety Notice** strongly advises the implementation of particular recommendations or solutions to improve quality and safety.

We recommend you inform:

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

Therapeutic Goods Administration (TGA) Recalls

Summary for May 2009

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

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

Class III – Class III defects 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.



May 2009

Class II Recall

ABL800 FLEX Blood gas analysers with a creatinine function (ABL817 FLEX, ABL827 FLEX and ABL837 FLEX) an in vitro diagnostic medical device (IVD)

ARTG number :

REFERENCE : RC-2009-RN-00334-3

DATE : 12/05/2009

COMPANY : Radiometer Pacific Pty Ltd.

REASON : In-house analysis of customer data by Radiometer has identified that the D711 reference membranes (product number 942-058) used in analysers measuring Creatinine have a reduced in-use lifetime.

PHONE : 03 9211 7333 – Carolyn Sloman.

ESTEEM BLUE with NEU-THERA Polyisoprene Surgeon Gloves

All lot numbers.

ARTG number: 109560

REFERENCE: RC-2009-RN-00336-3

DATE: 30/04/2009

COMPANY: Cardinal Health Australia 200 Pty Ltd.

REASON: Cardinal Health has recently identified through customer feedback, increased issues of cuff tears with the Esteem Blue with Neu-Thera Polyisoprene Surgeon Gloves.

PHONE: 02 9830 0124 – Mr Ty Bailey.

Dyonics Disposable Blades (used in orthopaedic surgery)

Various catalogue and lot numbers

ARTG number: 101031

REFERENCE: RC-2009-RN-00369-3

DATE: 11/05/2009

COMPANY: Smith & Nephew Surgical Pty Ltd

REASON: Potential breach of sterility in the product's primary packaging

PHONE: 02 9857 3944 - Matthew Thomas



Class II Recall (cont.)

D513 Disposable Waste Bottle; for Radiometer ABL8XX range of Blood Gas Analysers.

Lot Numbers:	WR-01	WS-01	WU-01	WY-01
	WR-02	WS-02	WU-02	
	WR-03	WS-03	WU-03	
	WR-04	WS-04	WU-04	
			WU-05	
			WU-06	

D512 Disposable Waste Bottle Part No.905-590 for Radiometer ABL7XX range of Blood Gas Analysers.

Lot Numbers :	WR-01	WS-01	WU-01
	WR-02	WS-02	WU-02
	WR-03	WS-03	WU-03

Part No: 905-802

REFERENCE: RC-2009-RN-00361-3

DATE: 7/05/2009

COMPANY: Radiometer Pacific Pty Ltd.

REASON: During production a number of waste bottles have had the vent holes closed. This may cause overpressure in the waste bottle and analyser.

PHONE: 1800 247 254 - Carolyn Sloman.

Philips Flex-M / Shoulder Coils for 1.5T MRI systems (used for digital imaging and diagnosis of patients)

ARTG number: 98887

REFERENCE: RC-2009-RN-00368-3

DATE: 11/05/2009

COMPANY: Philips Electronics Australia Ltd

REASON: The combined use of the Synergy Flex-M / Shoulder Coil 1.5T with other coils increase the chance of RF interaction and heating up of the coil which may result in possible burns to the patient.

PHONE: 1800 251 400 - Philips Customer Care Centre.

Class II Recall (cont.)

**4DITC Version 8.1.x or Varian Treatment (VT)
for Elekta, Siemens and GE Saturne Linacs Versions 6.6.5046 and
6.6.5048 with: ARIA server versions 8.1.15, 8.5.11 and 8.6.07
(oncology information systems for patient management)
Various Serial Numbers**

ARTG number: 132638

REFERENCE: RC-2009-RN-00371-3

DATE: 14/05/2009

COMPANY: Varian Medical Systems Australasia Pty Ltd

REASON: An anomaly was discovered in which a retired plan (former treatment plan) can be treated repeatedly.

PHONE: 1800 023 204 – Varian Technical Support.

**Abbott ARCHITECT Reaction Vessels
an in vitro diagnostic medical device (IVD)**

List Number: 7C15-01, Abbott Lot: 6838P100, Supplier Lot No: 6H9172101

REFERENCE: RC-2009-RN00380-3

DATE: 18/05/2009

COMPANY: Abbott Australasia Pty Ltd Diagnostic Division

REASON: Sponsor has observed an increase in complaints due to static discharge with the ARCHITECT reaction vessels at the ARCHITECT i2000, i2000SR and i100SR optics reader.

Signa MR Excite 1.5T systems loaded with 11.1_M4_0818.a software

ARTG Number : 108415

REFERENCE : RC-2009-RN-00414-3

DATE : 26/05/2009

COMPANY : GE Healthcare Australia Pty Ltd

REASON : A Scenario has been identified with the use of this MRI system software that may impact patient safety.

PHONE : 1800 659 465 – GE Customer Care Centre.

Class II Recall (cont.)

IMMULITE® 2000 and IMMULITE® 2500 Chemiluminescent Substrate

Lots	L2SUBM (Module)	L2SUBX (Bottle)
	282	253
	283	254
	284	255
	288	256A
	286	257A
	285	258
	287	259A

REFERENCE : RC-2009-RN-00400-3

DATE : 22/05/2009

COMPANY : Siemens Healthcare Diagnostics Pty Ltd.

REASON : These substrate lots have shown a tendency to introduce a shift in both control and patient results with multiple methods. The degree and direction of the shift in values is method dependent.

PHONE : 1800 358 030 – Siemens Customer Service.