



January 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 December 2008

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.



Class I Recall

Selected RF Ablation™ System Foot Switches (UPN M004218400, Catalog #21840) used with the Maestro 3000 Controller and the EPT-1000XP Controller. Foot switches that contain labels from Altech Corp are subject to this recall if the first five digits of the serial number are 07064 or lower.

(ARTG number 136695)

(REFERENCE: RC-2008-RN-00965-3)

Date: 26/11/2008

Reason: Boston Scientific discovered a short in the foot switch connector and it is possible that delivery of RF energy can begin without depressing the foot switch.

Further information: Boston Scientific Pty Ltd, 02 8063 8150 – Susana Diaz.

AQUARIUS Automated Fluid Balance Monitors

Models GEF08200 with Software Version 4.01.11 and 4.01.12 and

Models GEF09600 with Software Version 6.01

(ARTG number 144994)

(REFERENCE: RC-2008-RN-00984-3)

Date: 5/12/2008

Reason: 1. Haemoperfusion Set-up Instructions in Operating Manual, and Help instruction in Aquarius Software (version 4.01.11 and 4.01.12 only), display incorrect filter for set-up.

2. Total Fluid Balance Alarm can be overridden which could lead to hypovolaemia or hypervolaemia.

Further information: Edwards Lifesciences Pty Ltd, 1800 222 601 – Edwards Customer Service.

Various ConMed ABC® electrosurgical handpieces

Bend- α -Beam Single Function ABC® Handpieces (Catalogue Numbers: 134003, 134006, 134009)

Laparoscopic ABC® Handcontrol Probes (Catalogue Numbers: 160636, 160644, 160656)

Laparoscopic ABC® Footcontrol Probe (Catalogue Number: 160655)

Lot numbers 0306021 thru to Lot 0806021

(ARTG number: 136634 and 130869)

(REFERENCE: RC-2008-RN-01033-3)

Date: 24/12/2008

Reason: The manufacturer has been made aware of reports where the internal needle electrode is protruding from the ceramic insulator at the tip of the ABC® Handpiece. This protrusion could potentially result in an unforeseen risk to patients.

Further information: ConMed Linvatec Australia Pty Ltd, 1800 238 238 Kevin Samuels



Class I Recall (cont.)

ADVIA Centaur HIV 1/O/2 enhanced (EHIV) Assay used on the ADVIA Centaur or the ADVIA Centaur XP Immuno Assay systems, 200 Test Kit, REF 0463908

Lots 103031, 103033 and 103040

An invitro diagnostic medical device (IVD)

(ARTG number: 131954)

(REFERENCE: RC-2008-RN-01021-3)

Date: 22/12/2008

Reason: These reagent lots have shown instability regarding group O subtype HIV 1 reactivity.

Further information: Siemens Healthcare Diagnostics Pty Ltd, 1800 358 030 - Vince Chiera

Class II Recall

Flocare® Infinity Enteral Feeding Pump (EFP) with Software versions 2.07 up to 3.12 (inclusive)

(ARTG number 119667)

(REFERENCE: RC-2008-RN- 00953-3)

Date: 1/12/2008

Reason: Certain pumps may be affected by a software irregularity which can lead to the pump delivering feed at a higher flow rate than the rate programmed before starting the feeding.

Further information: Nutricia Australia Pty Ltd, 1800 060 051 – Nutricia Advanced Medical Nutrition.

Deltac Cozmo Insulin Pumps – Model 1800

All Serial Numbers

(ARTG number 98469)

(REFERENCE: RC-2008-RN-00961-3)

Date: 8/12/2008

Reason: Under Certain circumstances a lower than actual delivered amount of insulin will be displayed on 2 of the pump's display screens. At no time is delivery accuracy affected.

Further information: Medical Specialties Australia Pty Ltd - 02 9417 7955

Enzygnost® Anti-Helicobacter pylori II/IgG (OQOA)

Lot Numbers 37243, 37385, 37434 and 37653

(ARTG number)

(REFERENCE: RC-2008-RN-00971-3)

Date: 2/12/2008

Reason: Affected lots of this product show slightly increased frequency of positive results in the close cut-off range.

Further information: Siemens Healthcare Diagnostics Pty Ltd, 1800 358 030 – Chris Johnson.



Class II Recall (cont.)

Dimension® Clinical Chemistry System – Reaction Vessels

An in vitro diagnostic medical device (IVD)

Lots: NC16-182-08, NC16-196-08, NC16-210-08, NC16-217-08, NC16-231-08, NC16-245-08, NC16-189-08, NC16-203-08, NC16-224-08, NC16-238-08.

(ARTG number)

(REFERENCE: RC-2008-RN-00978-3)

Date: 2/12/2008

Reason: Siemens has confirmed a low frequency defect in the moulding of the HM Reaction Vessels that may result in a hole in the bottom portion of the vessel. Use of the defective reactions vessels could result in leakage of the reagent with subsequent various test report messages.

Further information:

Ferritin Reagent Cat No. OSR6150

Batches 5964, 5972, 6216, 6260, 6451, 6517, 6651 & 6771.

(ARTG number 114827)

(REFERENCE: RC-2008-RN-00981-3)

Date: 3/12/2008

Reason: Investigations by the manufacturer have shown that patient samples recover lower with these lots of reagent.

Further information: Integrated Sciences Pty Ltd, 1800 252 204 – Robert Apfel.

Table Mounts supplied with all IntelliVue Patient Monitors

Part Number M8000-64100, Select Units Only

(ARTG number 94238)

(REFERENCE: RC-2008-RN-00989-3)

Date: 9/12/2008

Reason: A limited number of Table Mounts have been assembled with screws that are too short. Screws that are too short may cause the Table Mount to break during installation or during adjustment of the monitor position.

Further information: Philips Electronics Australia Ltd – 1800 251 400 – Philips Customer Care.



Class II Recall (cont.)

ConMed – Optimizer Polypectomy Snares, and ConMed – Singular Polypectomy Snares

Catalogue numbers :

REF000462 REF000472 REF000474 REF000476
REF000957 REF000959 REF000963 REF000965
REF000977 REF000978 REF000983 REF000985
REF000987 REF000991

**Lot Numbers: Lot 0605011 through to and including Lot 0805311
(ARTG number 140908)**

(REFERENCE: RC-2008-RN-00994-3)

Date: 9/12/2008

Reason: The manufacturer has noticed an increase in complaints of snare (loop) detachment, due to insufficient crimping.

Further information: ConMed Linvatec Australia Pty Ltd – 1800 238 238 – Kevin Samuels

Block 2.0 STERRAD® 100S Sterilizers

All Units

(ARTG number 123603)

(REFERENCE: RC-2008-RN-00995-3)

Date: 9/12/2008

Reason: There are two situations, under rare circumstances, that could cause the STERRAD® 100S Sterilizers to malfunction.

Further information: Johnson & Johnson Medical Pty Ltd – 1800 252 194 ASP customer service team.

CADD Medication Cassette Reservoirs

100-ml Medication Cassette Reservoir; Reorder No 21-7002-24

Lot no. 213X18

(ARTG number 145297)

(REFERENCE: RC-2008-RN-00998-3)

Date: 15/12/2008

Reason: An increased trend of leakage is associated with one particular lot.

Further information: Smiths Medical Australasia Pty Ltd – 1800 654 949 – Lindsay Lindley

ENDOPATH® Electrosurgery Probe Plus II and a Laparoscopic Banding procedure kit containing this product – Selected items only

(ARTG number 125259 and 99301)

(REFERENCE: RC-2008-RN-00999-3)

Date: 10/12/2008

Reason: The manufacturer has identified that the stainless steel tips on the affected products were degrading, causing a small amount of nickel to be released, which may lead to health risks in some patients, particularly those with a known or suspected nickel allergy or sensitivity.

Further information: Johnson & Johnson Medical Pty Ltd – 1800 257 210 Georgina Ng.



Class II Recall (cont.)

INJECTOMAT TIVA AGILIA Infusion Pump Syringe

Serial numbers: 20133015-20346875

(ARTG number: 126194)

(REFERENCE: RC-2008-RN-01019-3)

Date: 22/12/2008

Reason: Software issues which could potentially affect patient safety

Further information: Pharmatel Fresenius Kabi Pty Ltd, 02 9391 5478 – Medical Information Pharmatel Fresenius Kabi

Feeding Kits containing a Grasping Snare

Specific Lot numbers only

Product Code	Lot Numbers	Product Code	Lot Numbers
000627	43EQA069	005729	43LQA101
	43FQA069		HURC9281
	43HQA070		HURC9529
	43HQA191		HURD0640
	43IQA074		HURD1797
	43JQA070		HURE3297
	43KQA092		HURE3298
	43LQA094		HURF0403
	HURB2394		HURJ0538
	HURD0626		HURJ1432
	HURE2809		HURK1454
	HURF0391		HUSA0272
	HURG1372		HUSA0273
	HURH0858		HUSC0638
	HURJ0535		HUSD1932
	HURL0222		HUSE1504
	HUSH1579		HUSF1736
005729	43ARA101		HUSG0963
	43FQA079		HUSG0964
	43IQA080		HUSH1585
	43JQA077		HUSH1586
	43KPA083		43KPA085
	43KPA084		43KQA101

(ARTG number: 141582)

(REFERENCE: RC-2008-RN-01020-3)

Date: 23/12/2008

Reason: The manufacturer has noticed an increase in complaints of snare (loop) detachment

Further information: Bard Australia Pty Limited, 1800 257 232 - Bard Australia Customer Service



Class II Recall (cont.)

Giraffe OmniBed infant incubator

(ARTG number: 139289)

(REFERENCE: RC-2008-RN-01009-3)

Date: 18/12/2008

Reason: Accumulation of debris and discoloration on component assemblies of Giraffe OmniBed devices, emphasizing the canopy seal area. In select instances, reported buildup of debris did indicate positive culturing for microorganisms that are common in healthcare environment.

Further information: GE Healthcare Australia Pty Ltd, 1300 722 229 – GE Service and Support Centre

Blizzard Active Wheelchair

(ARTG number: 129754)

(REFERENCE: RC-2008-RN-00963-3)

Date: 28/11/2008

Reason: The back-rest of the chair which extends underneath the seat can become loose and shear off the bolts holding it in place.

Further information: Otto Bock Australia Pty Ltd, 02 8818 2806 - Penny Knudson

Class III Recall

Take 1 Advanced Volume FS Dental elastometric impression material

Part no. 33887

Lot no. 80661-23

(ARTG number 95977)

(REFERENCE: RC-2008-RN-01012-3)

Date: 16/12/2008

Reason: One lot of Take 1 Advanced Volume FS has been produced with an excess amount of inhibitor which may affect the set time of the product.

Further information: Kerr Australia Pty Ltd – 1800 643 603