

1. DEVICE/EQUIPMENT:

3404 BCI® Autocorr® Plus pulse oximeter/ECG/respiration monitor.

Catalogue number: 3404002E

Serial numbers :

AI05070075, AI05070082, AI05070084, AI05110040, AI05110041,
AI05110042, AI05120001, AI05120002, AI05120007, AI05120008, AI05120009

No other models are known to be affected.

2. PROBLEM:

- A manufacturing error on the main board of the 3404 BCI® Autocorr® Plus pulse oximeter/ECG/respiration monitor will affect the following parameters:
- **SpO₂**: Electrical noise observed on the SpO₂ pleth waveform generating and displaying erratic heart rates. % SpO₂ reading displays dashes.
- **ECG**: The ECG waveform may appear noisy, ECG readings appear accurate.
- **Respiration**: The respiration waveform may appear noisy and the respiration readings will be displayed as dashes as the monitor is unable to learn the noisy waveform.

There may be no SpO₂, ECG or respiration waveforms displayed.

3. ACTION BY:

Anaesthetists, operating theatre practitioners, intensive care, A&E, ambulance and technical staff.

4. ACTION:

- Ensure you have received the Safety Action Bulletin 06-SAB07 from Smiths Medical (see appendix).
- Identify and quarantine devices with serial numbers as listed overleaf in the device section.
- Contact Smiths Medical to have any affected monitors repaired.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Operating Theatre Staff
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- Resuscitation Officers

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Jon Charters
Quality Assurance Manager
Smiths Medical International Ltd
Colonial Way
Watford WD24 4LG

Tel: 01923 246 434

E-mail: jon.charters@smiths-medical.com

Enquires to NIAIC should quote reference number MDEA(NI)2006/75 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

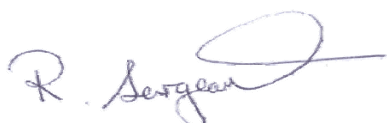
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 19 December 2006
Deadline (action underway)	: 29 December 2006
Deadline (action complete)	: 19 January 2007



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Appendix to MDEA(NI)2006-75

S.A.B. Tracking Number: 06-SAB07

[22nd November 2006]

Product/Catalog Number	Serial/Lot Number	Description
3404	See attached List	BCI® Autocorr® Plus Pulse Oximeter/ECG/Respiration Monitor

Distribution:

Internal Domestic External International External
(Eng/RA/QA/Dom/Int/OEM) Veterinary Division

Information:

POTENTIAL SAFETY ISSUE IDENTIFIED WITH 3404 BCI® AUTOCORR® PLUS PULSE OXIMETER/ECG/RESPIRATION MONITOR

To: Facility Administrator/Biomedical Engineering/Users of the 3404

We have identified a potential safety issue with the 3404 monitor. An error occurred at our board manufacturing site which may potentially affect the quality of the SpO₂ plethysmograph, ECG, and Respiration waveforms.

This error identified on the main board of the 3404 Autocorr® Plus Pulse Oximeter/ECG/Respiration monitor may affect the following parameters:

- **SpO₂:** An electrical noise observed on the SpO₂ pleth waveform generating and displaying erratic heart rates. % SpO₂ reading displays dashes.
- **ECG:** The ECG waveform may appear noisy, ECG readings appear accurate.
- **Respiration:** The respiration waveform may appear noisy and the respiration readings will be displayed as dashes as the monitor is unable to learn the noisy waveform.

Another potential affect will be no SpO₂, ECG, or Respiration waveforms displayed.

The monitor will produce appropriate alarms, alerting the clinician.

On all boards evaluated that produced any readings, the noisy waveforms provided ample evidence that something was wrong and the readings should be considered invalid.

Please forward a copy of this Safety Action Bulletin to any other personnel you may deem to be appropriate.

As a safety precaution, please take immediate action as indicated in the Distributor or User Actions Section.

We apologize for any inconvenience this may cause you and appreciate your cooperation in taking immediate action as indicated in the Distributor or User Actions to be Taken section of this bulletin.

Actions to be Taken by User or Distributor:

- I. Upon receipt of this Safety Action Bulletin, please send a written acknowledgement (See Page 3) that you have received this Safety Action Bulletin by return email (Mike.Rath@smiths-medical.com), mail, or fax to the attention of Michael Rath, Technical Service Manager.
- II. Verify the serial number(s) of your 3404 (BCI® Autocorr® Plus Pulse Oximeter/ECG/Respiration) monitor to see whether you have any of the affected monitor(s). Refer to the list of serial numbers of potentially affected monitors included with this bulletin. **If you are a distributor, immediately contain any monitors that you have not shipped to end-users.**

If the serial number(s) of your monitor(s) is not on the list, you do not need to take any further action.

- III. Bring this Safety Action Bulletin to the attention of all personnel who may use the device. If you are a distributor, you must inform your customers and instruct them to bring this to the attention of all users.
- IV. Contact Michael Rath, Technical Service Manager (262) 650-2975, at Smiths Medical PM, Inc. or your local distributor to make arrangements to have your 3404 (BCI® Autocorr® Plus Pulse Oximeter/ECG/Respiration) monitors repaired. When doing so, advise the Smiths Medical PM, Inc. Technical Service Manager of the serial numbers of the affected Advisor(s) that you have.
- V. If you are a distributor, also inform the Technical Service Manager of the quantity and serial numbers of the monitors that you have contained on site and what actions you have taken thus far to have the monitors that have shipped to customers returned for repair.

Should you have any questions concerning this request, please contact Smiths Medical PM, Inc. Technical Service Department using the contact information below.

Thank you for your cooperation.

Inspection/Testing Method (if applicable):

Not Applicable

Smiths Medical PM, Inc. markets a range of other patient monitors. These other monitors are NOT affected.

For further assistance contact:

Attention:
Smiths Medical PM, Inc. Telephone: (262) 542-3100
N7W22025 Johnson Drive Toll Free: (USA): (800) 558-2345
Waukesha, WI 53186-1856 Fax: (262) 542-0718
Email: info.pm@smiths-medical.com

URGENT MEDICAL DEVICE CORRECTION/REMOVAL

06-SAB07

22nd November 2006

**POTENTIAL SAFETY ISSUE IDENTIFIED WITH 3404
BCI® AUTOCORR® PLUS PULSE OXIMETER/ECG/RESPIRATION MONITOR**

Please complete the following with the correct information and return this response card by fax to **(262) 542-3325** by 8th December, 2006.

Smiths Medical. Account Number: (If Known) _____

Name of Facility: _____

Address of the Facility: _____

City: _____ State: _____ Zip: _____

Country: _____

Name: _____

Signature: _____

Title: _____ Date: _____

Phone: _____ Fax: _____

Check Actions Taken (Check all that apply):

- Acknowledge Receipt of this Safety Action Bulletin.
- Forward the Safety Action Bulletin to the appropriate department(s) and personnel.
- Identified affected Serial Numbers at our Facility.
- Quarantined affected Serial Numbers at our Facility
- Contacted the Smiths Medical PM, Inc. Technical Service Department for repair information.
- Other: _____

Serial Numbers Affected: _____

Fax to: Smiths Medical PM, Inc.
262-542-3325
Attn: Michael Rath, Technical
Service Manager
Reference: FY07-022, 06-SAB07

European Representative
Jon Charters
Quality Assurance Manager
Smiths Medical International Ltd
Colonial Way, Watford, WD24 4LG
Tel +44(0)1923 246434
E-mail jon.charters@smiths-medical.com