

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/20

Issued: 12 August 2003

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Datex-Ohmeda QUICK CAL calibration gas regulator	▶ ①
Problem: Risk of regulator becoming partially blocked, resulting in an incorrect monitor calibration.	▶ ②
Action by: Estates Managers with responsibility for medical device management, Medical Technical Officers and other technicians and staff responsible for calibration of monitors.	▶ ③
Action: <ul style="list-style-type: none"> Ensure that the maintenance of calibration gas regulators is in line with the manufacturer's instructions (Technical Bulletin REF#TB SABU HKI 02001 'Datex-Ohmeda Calibration Gas Regulators' published in February 2002; see Appendix) Be aware that regulators REF 755533 marked with the manufacturer's reference, starting RA-10D-2/ and ending in a five-digit serial number, are now obsolete. 	▶ ④
Distributed by NIAIC to: <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
Contacts NIAIC contact details	▶ ⑥
Feedback Requirements to NIAIC None	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Datex-Ohmeda calibration gas regulators used with QUICK CAL gas canisters for regulating the flow of calibration gas to calibrate multiparameter monitors.

Implicated regulators identification: REF 755534 (with a push button);
REF 755530 (with a rotary control valve).

Obsolete regulator identification: REF 755533 marked with the manufacturer's reference, starting RA-10D-2/ and ending in a five-digit serial number (with a rotary switch).

2. PROBLEM:

NIAIC has been informed that MHRA received an incident report where the use of a faulty calibration gas regulator produced a low concentration reading on the monitor. This regulator is now obsolete. However this problem also affects the current range of regulators. Datex-Ohmeda issued a Technical Bulletin in February 2002 to alert users to this potential problem and to provide new annual maintenance checks (see Appendix). However, this was not distributed in the UK until March 2003.

Datex-Ohmeda has identified that calibration gas regulators can become faulty over a period of time, due to small particles of aluminium and rubber from the canister screw and seal respectively, partially blocking the inside of the regulator. This results in insufficient gas being fed to the monitor. Therefore, air is entrained through the regulator's overflow port, diluting the calibration gas. The diluted calibration gas causes the incorrect calibration of multiparameter monitors.

3. ACTION BY:

Estates Managers with responsibility for medical device management, Medical Technical Officers and other technicians and staff responsible for calibration of monitors.

4. ACTION:

- Be aware of the Technical Bulletin REF#TB SABU HKI 02001 'Datex-Ohmeda Calibration Gas Regulators' published in February 2002 (see Appendix)
- Ensure that a system is in place for the maintenance of calibration gas regulators in line with the manufacturer's instructions.
- Regulators with REF 755533 marked with the manufacturer's reference, starting RA-10D-2/ and ending in a five-digit serial number are now obsolete. These devices should be replaced with new style regulators REF 755534.

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:

- Estates Managers
- Medical Technical Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Device/Equipment Co-ordinators
- Medical Directors
- Nurse Directors
- Accident & Emergency Departments
- Directors of Anaesthetics
- Anaesthetists
- Theatre Managers
- All Intensive Care Units
- Providers of Private Health Care – Private Clinics/Hospitals

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/20 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:

None Required



Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2003/01. 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

REF#TB SABU HKI 02001

Datex-Ohmeda Calibration Gas Regulators (REF 755534 & 755530)

Dear Addressee,

Please find below new annual maintenance instructions concerning the Datex-Ohmeda calibration gas regulators, REF 755534 & 755530. These regulators are used for a variety of calibration gases for Datex-Ohmeda monitors.

The new recommended annual maintenance for the calibration gas regulators is a flow check.

In the past all the regulators have been considered as products that did not require periodic maintenance.

These new instructions will be applicable immediately to the entire installed base of the regulators.

We have identified a few calibration gas regulators, that have become faulty over a period of time in a way that the customer might not readily detect. It is possible, that over time very small aluminium and rubber particles enter the inside of the regulator resulting in it becoming partially blocked. The aluminium and the rubber both originate from the calibration gas cans, where the aluminium is from the top screws and the rubber is from the top seal.

The usage of blocked calibration gas regulators will result in a faulty monitor calibration. This is because during gas calibration the monitor suctions gas from the sampling line connected to the regulator at a steady rate and in case of blocked or partially blocked regulator, the regulator cannot feed enough calibration gas to the monitor. If this is the case, then air enters the sampling line through the regulator overflow port resulting the monitor analyzing calibration gas diluted with room air. The end result is that the monitor has been calibrated incorrectly and the monitor readings will be higher compared to the real gas concentration.

Datex-Ohmeda has not received any allegation or claim that the reported situation caused or contributed directly or indirectly to a death or serious injury or compromise the patient safety. Due to faulty calibration regulator, the device displays incorrect high readings after calibration.

The new recommended annual maintenance for the calibration gas regulators is a flow check. If the flow rate is not within specification, then the regulator needs to be replaced by a new one. There is no service or repair that can be done to the faulty regulators. If the warranty is still valid, then the regulator will be replaced FOC. The warranty for new regulators is 12 months.

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Maintenance type: Flow check

Interval: every 12 months

Regulator flow specification:

- REF 755534: 260 – 410 ml/min at 1-10 bar cylinder pressure
- REF 755530: 260 – 410 ml/min at 5 – 7 psi cylinder pressure

Tools needed: calibration gas can, regulator, piece of silicon hose and a flow meter. Datex-Ohmeda recommends to use TSI 4140 Flow Meter.

How to measure the regulator flow:

Insert the calibration gas regulator to the calibration gas cylinder. Connect a silicon hose between the regulator and the flow meter. **Block the regulator overflow port** and open the regulator. Check the flow rate from the flow meter and verify that the flow is within the specification.

Yours sincerely,

Niko Nuotio

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Make the right connection

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