

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/39

Issued: 9 December 2003

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Diametrics Medical Ltd Neotrend L multiparameter neonatal sensor N7004L</p>	▶ ①
<p>Problem: Damage to the tip of the sensor resulted in a fragment being left in a major blood vessel of two neonates.</p>	▶ ②
<p>Action by: All medical and nursing staff in special care baby units and neonatal intensive care units.</p>	▶ ③
<p>Action: When removing the sensor from an umbilical artery catheter (UAC) which is to remain in-situ, ensure that the sensor has been fully retracted before clamping the UAC with a soft tubing clamp or bending it over at an extended section. Wherever possible, remove the UAC and sensor together (see Appendix). HPSS Trusts should put in place an implementation plan to ensure that all staff have undertaken the actions described above and the actions are incorporated into training plans for new staff.</p>	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC If anything adverse occurs whilst using this device, report the incident to NIAIC and retain the device and associated devices as recommended in SN(NI)2003/01.</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Diametrics Medical Ltd Neotrend L multiparameter neonatal sensor for continuous measurement of blood parameters (pH, pCO₂, PO₂ and temperature), used to monitor the condition of neonates in special care baby units and neonatal intensive care units.

2. PROBLEM:

NIAIC has been informed that the Medicines and Healthcare products Regulatory Agency (MHRA) has received two reports of damage to the tip of the sensor resulting in a fragment being left in a major blood vessel of two neonates.

The device involved in the first incident was discarded but the fragment remains in-situ. Consequently no conclusions can yet be drawn as to the reason for damage to the sensor.

Following an examination of the umbilical artery catheter and the sensor involved in the second incident, it is likely that a clamp may have been applied to the catheter before the sensor was fully retracted. Trapping the sensor in the clamp whilst removing it from the catheter may have caused the sensor to fracture.

3. ACTION BY:

All medical and nursing staff in special care baby units and neonatal intensive care units.

4. ACTION:

When removing the sensor from an umbilical artery catheter (UAC) which is to remain in-situ, ensure that the sensor has been fully retracted before clamping the UAC with a soft tubing clamp or bending it over at an extended section. Wherever possible, remove the UAC and sensor together (see Appendix).

HPSS Trusts should put in place an implementation plan to ensure that all staff have undertaken the actions described above and the actions are incorporated into training plans for new staff.

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Nurse Directors
- Medical and Nursing Staff
- Special Care Baby Units
- Neonatal Intensive Care Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Ms Jan Walters or Mr Graham Howard
Diametrics Medical Ltd
Short Street
High Wycombe
HP11 2QH

Tel: 01494 471671

Fax: 01494 474890

E-mail: jwalters@dmltech.co.uk
[ghoward@dmltech.co.uk](mailto:goward@dmltech.co.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2003/39 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:

If anything adverse occurs whilst using this device, report the incident to NIAIC and retain the device and associated devices as recommended in SN(NI)2003/01.



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



N7004L Neotrend-L Sensor Removal

Abstract from A1145-01 Neotrend-L Multiparameter Sensor Instructions for Use

Section 4: Precautions

“Excessive force must not be used to remove the sensor. Use of excessive force to remove the sensor has the potential risk of sensor separation. If on sensor removal, resistance is felt, determine the cause of the resistance and take appropriate steps to rectify. When necessary, remove the sensor and umbilical artery catheter concurrently.”

Section 8: Sensor Removal

“Disconnect PDM from sensor.

1. Wherever possible remove the UAC and sensor together, however if medically warranted the sensor can be retracted without removal of the UAC.
2. Remove all securing devices anchoring sensor, being careful not to dislodge UAC.
3. Turn rear clamp (blue nut) (G) counter clockwise one full turn to open seal.
4. Depress black button on advancement lock (I) exposing white button to release sensor.
5. Slowly pull the advancement lock while holding the ‘Y’ pressure port until the sensor is fully retracted. If undue resistance is met during retraction:
 - a) Ensure rear clamp and advancement lock are in unlocked position.
 - b) Place UAC and sensor in a straight line configuration.
 - c) Ensure UAC is not constricted by anchoring technique, i.e. sutures

If undue resistance is still met after re-evaluation, remove the sensor and UAC together as one unit.

6. Crimp or clamp UAC with appropriate device below hub and disengage luer fittings between sensor and UAC”

Use of clamps

In accordance with the Instructions for Use, clamp off the UAC by either bending over at extended section, or a **soft tubing clamp**.

Adson forceps for clamping **umbilical stump only**.

Do not use forceps/surgical clamps on umbilical catheter.



Reg No. FM 22859

Short Street
High Wycombe
Bucks. HP11 2QH
England
Tel: 44 (0) 1494 471671
Fax: 44 (0) 1494 474890

Registered in England No. 1676781