

Medical Device Alert

Action

Ref: MDA(NI)2009-013 Issued: 18 February 2009 at 15:00

Device

Unomedical Unilect 4831Q and 4841P short term adult and paediatric ECG monitoring electrodes.



Problem

Degradation in performance after defibrillation.

Following defibrillation the observed ECG waveform may show a 'flatline' (asystole). This may result in inappropriate treatment that could be detrimental to the patient.

Action by

Users of defibrillators and ECG equipment.
Those responsible for medical device management.

SABS deadlines

Action underway: 25 February 2009
Action complete: 18 March 2009

Action

- Remove from use all Unomedical Unilect 4831Q and 4841P electrodes.
- Return them to your distributor/supplier for credit or replacement with an alternative product.

Contact

Manufacturer
Debbie Mertens
Quality Assurance
Unomedical Ltd

Tel: 01527 587 700 ext: 7747
Email: debbie.mertens@unomedical.com

Device

The 4831Q is an adult and paediatric short term, foam monitoring electrode.

The 4841P is an adult short term, foam monitoring electrode with a radio-translucent connector.

Both are used primarily with ECG monitors but can also be used with manual defibrillators with paddles that monitor ECG via separate electrodes.

Problem

Unomedical is recalling these electrodes and has issued an urgent Field Safety Notice to UK distributors (see appendix).

The 4831Q electrodes show a degradation of normal performance when subjected to testing. This includes failure with regard to DC offset voltage and defibrillation overload recovery.

The cause has been identified as seepage of the conductive gel, leading to electrolytic corrosion.

It has been found that 25% of returned 4831Q electrodes are affected, although there have been no adverse incidents reported.

Unomedical is also unable to guarantee the performance of the 4841P electrodes so these are also being recalled as a precaution. However, none of the returned 4841P electrodes have shown the failure mode identified.

Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

Onward distribution

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

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- | | |
|--------------------------------|--|
| • A&E departments | • Medical physics departments |
| • All departments | • Midwifery departments |
| • All wards | • Neonatology directors |
| • Ambulance services directors | • Nursing executive directors |
| • Ambulance staff | • Obstetrics and gynaecology directors |
| • Anaesthesia, directors of | • Obstetrics departments |
| • Dental departments | • Paediatric intensive care units |
| • EBME departments | • Paediatric medicine, directors of |
| • Equipment stores | • Paramedics |
| • Health and safety managers | • Purchasing managers |
| • In-house maintenance staff | • Resuscitation officers and trainers |
| • Intensive care units | • Risk managers |
| • Intensive care, directors of | • Supplies managers |
| • Maintenance staff | • Theatre managers |
| • Maternity units | |
| • Medical directors | |

The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- All Nursing Home providers
- Domiciliary care providers
- Independent treatment centres
- Nursing agencies

Boards to:

SABS liaison officers for onward distribution to:

- Risk manager

Central Services Agency (CSA) to:

SABS liaison officers for onward distribution to all relevant staff including:

- Staff with responsibility for purchasing

Contacts

Manufacturer

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NIAIC

Enquiries in Northern Ireland, please send enquiries about this notice to the NIAIC quoting reference number **MDA(NI)2009-013** and addressed to:

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

Tel: 02890 523868
Fax: 02890 523900
E-mail: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the NIAC website

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

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APPENDIX**URGENT FIELD SAFETY NOTICE**

Commercial name: Unomedical Unilect 4831Q and 4841P Short Term Monitoring Electrode
LOT No: All
FSCA Id: MHRA Ref: 2008/010/023/061/011 Unomedical Ref: E08-037
Type of action: Recall

Date: 31 October 2008

Details of affected devices:

Unilect 4831Q Short Term Monitoring Electrodes Ref No.: 1000930180
Unilect 4841P Short Term Monitoring Electrodes Ref No.: 1000920180

Description of the problem:

Unomedical recently discovered a problem with samples of the 4831Q electrode which typically show a degradation of normal performance when subject to testing for defibrillation recovery. Therefore, when using the electrode for ECG monitoring purposes the clinician will not observe the ECG signal since the DC offset potential is larger than the magnitude of the signal itself.

If an electrode is attached to the patient who may require resuscitation through the use of a defibrillator, the resultant currents applied to the ECG electrode during the 'electrical shock' will further degrade the performance of the electrode, damaging the ability of the electrode to regain its ECG capability. As a consequence, the resultant 'flatline' on the ECG monitor may prompt the clinician to attempt a further defibrillation of the patient, which may be unnecessary.

No adverse incidents are known, but we have decided to initiate a recall, in order to maintain the integrity and reliability of our product. As we are unable to be certain that the 4841P variant could not develop this problem, we consider that it is prudent to recall this electrode also.

Instruction on action to be taken by the End User:

1. Please stop the use of all 4831Q and 4841P products you may have.
2. Check stock and complete the enclosed questionnaire which should be forwarded to your Distributor by Friday 21 November 2008.
3. Return all 4831Q and 4841P products to Distributor for credit by 21 November 2008 .

Transmission of this Field Safety Notice:

Unomedical apologises for any inconvenience this may cause and requests that you share this Notice with all Unilect 4831Q and 4841P users at your facility. If you have any questions, please call your local Distributor or Unomedical representative.

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