

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/79

Issued: 7 November 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Footswitches for use with all models of ConMed or Valleylab electrosurgical units (ESUs), including footswitches manufactured by third parties.</p>	▶ ①
<p>Problem: ConMed and Valleylab ESUs share the same type of footswitch connector but are wired differently. If the footswitches intended for one type of ESU are used with the other, the ESU will deliver 'cut' waveforms when the 'coagulate' footswitch is depressed, or 'coagulate' waveforms when the 'cut' footswitch is depressed.</p>	▶ ②
<p>Action by:</p> <ul style="list-style-type: none"> Theatre staff. Staff responsible for routine testing and maintenance of ESUs (e.g. electrical and biomedical engineering / clinical engineering / medical physics / estates departments). 	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Theatre staff should check, before use, that footswitches operate cut and coagulate outputs correctly as advised in the manufacturer's instructions for use. Maintenance staff should ensure that all footswitches are labelled for use with the appropriate ESU. 	▶ 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 For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturers' contacts, NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required.</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Footswitches for use with all models of ConMed or Valleylab electrosurgical units (ESUs), including footswitches manufactured by third parties.

2. PROBLEM:

ConMed and Valleylab ESUs share the same type of footswitch connector but are wired differently. If the footswitches intended for one type of ESU are used with the other, the ESU will deliver 'cut' waveforms when the 'coagulate' footswitch is depressed, or 'coagulate' waveforms when the 'cut' footswitch is depressed.

3. ACTION BY:

- Theatre staff.
- Staff responsible for routine testing and maintenance of ESUs (e.g. electrical and biomedical engineering / clinical engineering / medical physics / estates departments).

4. ACTION:

- Staff should, as part of planned preventative maintenance, check that footswitches operate the correct cut and coagulate outputs.
- Report to the MHRA and the manufacturer any instance where the labelling is not sufficient.

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
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Operating Theatre Staff
- Accident & Emergency Departments
- Day Procedure Units
- EBME Departments
- Medical Physics Departments
- All Surgeons
- Theatre Managers

6. CONTACTS:

Enquiries to the manufacturers should be addressed to:

ConMed:

Pam Vetter

ConMed Corporation

14603 East Freemont Avenue

Centennial

Colorado 80112

USA

Tel: 00 1 303 269 8229

Fax: 00 1 303 699 9854

E-mail: pam_vetter@es.conmed.com

Valleylab:

Bob Moore

Valleylab

5920 Longbow Drive

Boulder

Colorado 80301-3299

USA

Tel: 00 1 303 530 6241

Fax: 00 1 303 530 6285

E-mail: bob.moore@tycohealthcare.com

Enquires to NIAIC should quote reference number MDEA(NI)2005/79 and be addressed to:

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

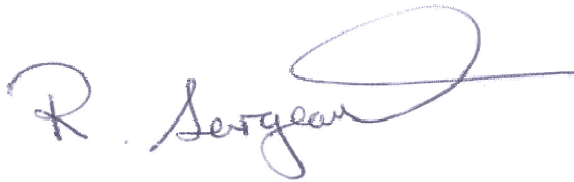
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.

A handwritten signature in blue ink that reads "R. Sergeant". The signature is fluid and cursive, with a large loop at the end.

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)2005/01. 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

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