

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/19

Issued: 1 August 2003

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Allied Healthcare Products manual resuscitator/self inflating resuscitation bag	▶ ①
Problem: Manufacturing fault resulting in the fracture of the connector that attaches the mask to the bag during use, leaving the manual resuscitator inoperable.	▶ ②
Action by: All those that use resuscitation equipment.	▶ ③
Action: Recall of model number L570-040, lot numbers 000431 000451	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers General Dental Practitioners Hospices	▶ ⑤
Contacts NIAIC contact details	▶ ⑥
Feedback Requirements to NIAIC None Required but please inform your supplier if you have an Allied Healthcare Products, LSP, adult disposable bag mask resuscitator, lot numbers 000431 and 000451.	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Allied Healthcare Products, Life Support Products (LSP), adult disposable bag mask resuscitator.
Allied Healthcare Products product code: L570-040
Lot numbers: 000431 and 000451

Blackwell Supplies have distributed the manual resuscitators both individually and within emergency oxygen kits. Blackwell Supplies product code is L07297.

2. PROBLEM:

NIAIC has been informed that MHRA has received several incident reports where the connector holding the mask in place broke and the mask disconnected from the manual resuscitator bag. This rendered the manual resuscitator inoperable.

This failure resulted from a change in the material used for the connector leading to difficulties in welding the mask adaptor to the connector. Once the manufacturer identified the problem a return was made to the original material. A recall was initiated on the potentially faulty devices affecting lot numbers 000431 and 000451.

There are two distributors in the UK, Draeger Medical Ltd and Blackwell Supplies Ltd. Draeger Medical have confirmed that all resuscitators they have distributed with these lot numbers have been recalled. However Blackwell Supplies, despite sending a recall notification to customers, cannot confirm that the relevant manual resuscitators have been recalled.

NIAIC understands from MHRA that the majority of these customers are dentists in primary care but as there is the possibility of other sources of distribution and potential customers in the primary care area in Northern Ireland, this Alert has been issued to all NIAIC Liaison Officers for action if appropriate.

The only other European distributors are APOX VOF in the Netherlands and SMSP in France.

3. ACTION BY:

All those that use resuscitation equipment.

4. ACTION:

- Please check whether you have any Allied Healthcare Products LSP adult disposable bag mask resuscitators.
- Remove all resuscitators with lot numbers 000431 and 000451 from use.
- Ensure that an appropriate resuscitator is substituted immediately.
- Perform pre-use checks to confirm the correct operation.

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 Device/Equipment Co-Ordinators
- Medical Directors
- Nursing Directors
- All wards and departments
- Resuscitation Officers
- Independent Health and Social Care Providers including residential, nursing homes and private clinics
- Directors of Public Health
- Practice nurses
- District nurses
- Health visitors
- Practice Managers

6. CONTACTS:

Enquiries to the supplier should be addressed to:

Mr R Fuller
Blackwell Supplies Ltd
Medcare House
Centurion Close
Gillingham Business Park
Gillingham
Kent, ME8 0SB

Tel: 01634 877620

Fax: 01634 877621

E-mail: rodfull@henryschein.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2003/19 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:

Please inform your supplier if you have an Allied Healthcare Products, LSP, adult disposable bag mask resuscitator, lot numbers 000431 and 000451.



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